Biotech Daily

Tuesday April 29, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NANOSONICS UP 6%, OPTISCAN DOWN 10%**

*** GENERA WELCOMES COMMITTEE HPV TESTS RECOMMENDATION**

*** BIO-MELBOURNE NETWORK TO LOSE CEO MICHELLE GALLAHER**

*** MESOBLAST TO EXPEDITE US PROCHYMAL APPROVAL, CROHN'S TRIAL**

*** NANOSONICS Q3 SALES UP 24%**

*** SPECIALISED THERAPEUTICS TO DISTRIBUTE PSIVIDA, ALIMERA ILUVIEN**

*** CLARIFICATION: OBJ, PROCTOR & GAMBLE DEAL**

*** VIRAX APPOINTS PROF JASON SMYTHE SCIENTIFIC ADVISOR**

*** BIOPROSPECT APPOINTS VINCE FAYAD CHAIR, NEW BOARD, EXECUTIVE**

MARKET REPORT

The Australian stock market fell 0.89 percent on Tuesday April 29, 2014 with the S&P ASX 200 down 49.5 points to 5,486.6 points.

Seven of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and four were untraded.

Nanosonics was the best, up 4.5 cents or 5.6 percent to 85 cents with 854,734 shares traded, followed by Prima up 5.4 percent to 3.9 cents, with 1.9 million shares traded.

Atcor climbed 4.2 percent; Bionomics was up 3.45 percent; Benitec and Impedimed rose more than two percent; with Resmed and Tissue Therapies up more than one percent.

Optiscan led the falls, down half a cent or 10 percent to 4.5 cents with 18,174 shares traded.

GI Dynamics, Prana and QRX lost seven percent or more; Antisense fell 6.9 cents; Universal Biosensors shed 5.3 percent; Anteo and Ellex fell more than four percent; Living Cell, Neuren and Reva were down more than three percent; Genetic Technologies, Medical Developments and Sirtex shed two percent or more; Alchemia, Mesoblast, Oncosil and Pharmaxis were down more than one percent; with Acrux, Clinuvel, Cochlear and CSL down by less than one percent.

GENERA BIOSYSTEMS

Genera says the Medical Services Advisory Committee has recommended that the human papillomavirus tests replace the Pap smear as the primary cervical cancer screening tool.

Genera, which has been developing the Paptype human papillomavirus (HPV) test to detect the virus and simultaneously genotype high risk HPV types, said that the recommendation followed a three year renewal review program that began in 2011.

In 2010, the Australian Therapeutic Goods Administration approved the Paptype test kit for the Australian Register of Therapeutic Goods. (BD: Jan 22, 2010).

Today, Genera said that the Medical Services Advisory Committee findings of the long term evaluation suggested that improved cost and effectiveness outcomes could be achieved within the National Cervical Screening Program in Australia, by primary HPV screening with either cytology triage for all oncogenic types or with partial genotyping.

The company said that one of the most effective strategies of any evaluated overall involved primary HPV screening with simultaneous partial genotyping for HPV 16 and 18.

Genera said that the Committee recommended the adoption of a five-yearly cervical screening program using a primary HPV test with partial HPV genotyping and reflex liquid-based cytology triage, for HPV vaccinated and unvaccinated women aged 25 to 69 years, with exit testing of women aged 70 to 74 years.

The company said that according to the Committee a strategy involving primary HPV screening with partial genotyping and an extended screening interval would result in a 45 to 51 percent decrease in the average lifetime number of screening or follow up tests per woman in the population, compared to current practice, with expected cost savings in the order of $50 million a year.

Genera said the review and recommendation assumed that the volume of HPV tests in Australia would increase 40-fold from the current level of about 31,000 a year to about 1.25 million with an assumed reimbursed cost per test of $30.00 compared to the current rate of $63.55 as economies of scale were delivered.

The company said that if the Committee recommendations were accepted, HPV testing in Australia would become a substantial commercial opportunity from 2016.

Genera said it would begin discussions with relevant stakeholders with a view to ensuring that the benefits offered by Paptype, which simultaneously genotypes all 14 high risk HPV types, were available to Australian women.

The company said that full genotyping was an important differentiator of the Paptype test and while HPV types 16 and 18 accounted for 70 percent of cervical cancer, full genotyping of high risk types that caused 99.7 percent of all cervical cancer had the potential to substantially increase specificity of an HPV test, particularly when used within a long-term screening program.

Genera executive chairman Lou Panaccio said the recommendations “are good news for Australian women as HPV testing has the potential to provide superior patient outcomes together with extended screening intervals”.

“This is also an exciting time for Genera as we have spent a decade developing and refining Paptype, a unique next generation HPV test,” Mr Panaccio said.

“The potential benefits of Paptype are increasingly recognized by global opinion leaders, and we will be working hard to ensure that our test is ready for use in high-volume Australian pathology laboratories in advance of the [Committee] recommendations being implemented,” Mr Panaccio said.

Genera said it expected TGA and Conformité Européenne (CE) mark registration of the solid phase version of Paptype during 2014 with plans to launch the product in Australia, Europe and South America in 2014 and 2015.

Genera was up one cent or 7.1 percent to 15 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that chief executive officer Michelle Gallaher will resign in July 2014 to become “a start-up entrepreneur in her own business”.
Bio-Melbourne Network chairman Andrew Macdonald said that in July Ms Gallaher would have been its chief executive officer for six years “and during that time has left an indelible mark on our sector with her enthusiasm, drive and passion”.
Mr Macdonald said that Ms Gallaher had led the organization through a period in which it had consolidated and grown its value to members and stakeholders in the Victorian biotechnology sector.
Mr Macdonald said that Ms Gallaher had advanced and diversified the membership group with membership in April close to a record high, the financial position secure and a strategic plan that mapped out a clear growth path for the future.
Mr Macdonald said the organization would begin a search for a new chief executive officer “I offer our very best wishes to Michelle in her new venture and look forward to her continuing involvement with the Network,” Mr Macdonald said. “She leaves the Bio-Melbourne Network in a strong and sustainable position with enormous good will in which she has played a pivotal part in building and should be very proud of this legacy.”

MESOBLAST

Mesoblast says it will meet with US regulators to accelerate approvals for Prochymal for graft versus host disease, as well as continue a phase III Prochymal Crohn’s disease trial.
Mesoblast said it acquired Prochymal as part of the Osiris Therapeutics mesenchymal stem cell business last year (BD: Oct 11, 2013).
The company said that one reason for the acquisition was “the potential for early and significant revenue streams using Prochymal, the world’s first approved allogeneic stem cell therapeutic and the only allogeneic stem cell therapeutic designated by the US Food and Drug Administration as both an orphan drug and fast track product”.
Mesoblast said that major drivers for the transaction were the evaluation of the use of Prochymal for inflammatory diseases of the bowel, including patients with Crohn’s disease who had failed other biologic agents and patients with potentially life-threatening graft versus host disease involving the gut and liver after a bone marrow transplant.
Prochymal is available in the US under a special access scheme for children with graft versus host disease GvHD and has been shown to increase survival (BD: Nov 14, 2013).
Mesoblast said it would meet with FDA “shortly, to discuss potential pathways for accelerated Prochymal product approvals in the US for the treatment of steroid-refractory acute GvHD, a disease with inflammatory etiology and a significant gastrointestinal component”.
The company said that Japan collaborator JCR Pharmaceuticals was expanding its manufacturing facility for its 2015 launch of its mesenchymal stem cell product JR-031 for steroid-refractory acute graft versus host disease, which was granted orphan drug status in December 2013 and would be the subject of an expedited review.
Mesoblast said that an internal review of the Crohn’s disease program reinforced its intention to complete an ongoing phase III trial of adult patients refractory to treatment with steroids, classic immuno-suppressives and biologic therapy.
The company said it expected to have a readout by the end of the year on whether the primary endpoint of day-28 remission in biologic-refractory patients had been achieved, whether there was evidence of efficacy in high-risk groups such as those with fistulizing disease and whether repeat dosing could result in longer-term maintenance of effect.
Mesoblast fell eight cents or 1.7 percent to $4.67 with 490,856 shares traded.

NANOSONICS

Nanosonics says sales for the three months to March 31, 2014 were up 24 percent to $5,220,000 compared to the prior corresponding period.
Nanosonics chief executive officer Michael Kavanagh told a teleconference that the revenue for the first nine months of the 2013-'14 financial year was equal to the full previous year and the company had a strong cash balance.
Mr Kavanagh said that 1,415 US healthcare facilities had adopted the company's Trophon EPR ultrasound probe cleaning system.
Mr Kavanagh said that the facilities were primarily hospitals along with radiology practices and other private clinics.
He said that the Trophon EPR was certified for 500 different probes including obstetrics and gynaecology, urology, surgery and biopsy.
Mr Kavanagh said that 11 hospitals in the UK had adopted the Trophon EPR but unlike the US, the UK institutions tended to make multiple purchases.
Mr Kavanagh said that Miele Professional had launched the Trophon EPR in Germany.
Mr Kavanagh said that a European Parliament resolution including advice to adopt optimal care for infection control was supported unanimously but that did not force countries to implement the recommendations (BD: Aug 20, 2013).
"The European Parliament voted in favor of recommendations on patient safety including the prevention and control of healthcare associated infections," Mr Kavanagh said.
"Part of these recommendations call for optimum decontamination of medical instruments and devices," Mr Kavanagh said.
"This would include high level disinfection of ultrasound probes," Mr Kavanagh said.
Nanosonics said it had a net operating cash inflow of $2,220,000 in the three months to March 31, 2014, with a total of $23,762,000 in cash.
Nanosonics was up 4.5 cents or 5.6 percent to 85 cents.

PSIVIDA

Psivida says that Specialised Therapeutics Australia with distribute licensee Alimera Sciences' Iluvien for diabetic macular oedema in Australia and New Zealand.
Psivida said that that Specialised Therapeutics would handle all regulatory and commercial activities for Iluvien in Australia and New Zealand.
The company said that the agreement included a milestone payment to Alimera for achievement of a public reimbursement listing and royalties based on net sales that would increase pending sales targets.
Psivida said it was entitled to 20 percent of royalties and 33 percent of all other payments received by Alimera, including milestones.
Psivida was untraded at $4.00.

OBJ

Last night's edition reported that OBJ had agreements with Procter and Gamble for its magnetic micro-array technology for unnamed products.
At the time of publication no one from OBJ had been able to confirm the intended use of its technology for Procter and Gamble which has a diverse range of consumer products.
After publication OBJ chairman Glyn Denison told Biotech Daily that the details of the agreements were confidential but said: "OBJ's technologies are all designed for transdermal delivery of clients' formulations and that will include Proctor and Gamble."
OBJ was up 1.4 cents or 18.2 percent to 9.1 cents with 85.7 million shares traded.

VIRAX HOLDINGS

Virax says it has appointed Prof Jason Smythe to its scientific advisory team to consult on the Co-X-Gene immunotherapeutic platform.
Virax said that Prof Smythe would advise on the development of new intellectual property and future protection of the Co-X-Gene platform.
The company said that Prof Smythe had more than 25 years research and senior management experience in the biotechnology sector in Australia and the US.
Virax said that Prof Smythe had held senior research and development management positions and directorships at research institutions including the Commonwealth Scientific and Industrial Research Organisation and biotechnology companies including Benitec and Australian Tissue Engineering Centre developing innovative gene technology products.
The company said that Prof Smythe had published more than 30 manuscripts and had been granted five patents.
Virax said that since 2004 Prof Smythe had been a member of the Federal Government Gene Technology Technical Advisory Committee reporting to the Gene Technology Regulator.
The company said that Prof Smythe held a Bachelor of Science from Monash University, a Doctorate of Philosophy from the Walter and Eliza Hall Institute for Medical Research and performed his post-doctoral research at the National Institute of Health in Bethesda, Maryland.
Virax fell 0.1 cents or 10 percent to 0.9 cents with 3.5 million shares traded.

BIOPROSPECT

Bioprospect says it has appointed a new board and executive to commercialize the Invatech heart rate variability technology to diagnose depression and mental disorders.
Bioprospect said that PKF Lawler Corporate Finance director Vince Fayad had been appointed as non-executive chairman.
The company said that Claude Solitario co-founded Invatec Health in 2005 with Dr Stephen Addis and had been appointed an executive director.
Bioprospect said that as an Invatec director, Mr Solitario continued to receive an annual salary of $250,000 under an existing contract of employment and no additional remuneration was payable by Bioprospect at this stage.
The company said that despite shareholder approval to appoint Dr Addis as a director, Dr Addis has advised that his commitments precluded him from joining any public company board.
Bioprospect said that Stephen Stapelberg had been appointed commercial development manager to oversee the commercialization of the heart rate variability technology, marketing and public relations.
The company said that Peter May and Silvi El-Khouri would continue as non-executive directors.
Bioprospect was unchanged at 0.3 cents with 1,750,000 shares traded.