Biotech Daily

Tuesday December 9, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 13%**
- GENETIC TECHNOLOGIES DOWN 12%

*** ANTISENSE ATL1103 ACROMEGALY TRIAL, ATL1102 MS ACCESS, PARTNERS**

*** CE MARK FOR UNIVERSAL BIOSENSORS SIEMENS COAGULATION TEST**

*** GI DYNAMICS 'SEPARATES' CFO BOB CRANE, CUTS 10% STAFF**

*** IMUGENE $834k PLAN, $500k PLACEMENT TAKE TOTAL TO $3.6m**

*** BONE REJECTS BN006 FOR RHEUMATOID ARTHRITIS**

*** ALCHEMIA APPOINTS CONSULTANTS FOR VAST 'TRANSACTION'**

*** COCHLEAR APPOINTS GLEN BOREHAM, ALISON DEANS DIRECTORS**

MARKET REPORT

The Australian stock market fell 1.68 percent on Tuesday December 9, 2014 with the S&P ASX 200 down 90.0 points to 5,282.7 points.

Just five of the Biotech Daily Top 40 stocks were up, 23 fell and 12 traded unchanged.

Universal Biosensors was the best, up two cents or 12.9 percent to 17.5 cents with 1.4 million shares traded, followed by Clinuvel up 11.7 percent to $4.30 with 49,555 shares traded.

Atcor climbed 10 percent; Optiscan was up 4.55 percent; Cochlear rose 1.2 percent with Medical Developments and Resmed up by less than one percent.

Genetic Technologies led the falls, down 0.2 cents or 11.8 percent to 1.5 cents with 216,000 shares traded, followed by Antisense down 10.5 percent to 8.5 cents with 270,809 shares traded.

IDT lost 8.3 percent; GI Dynamics fell 7.0 percent; Bionomics and Patrys were down more than six percent; Benitec and Mesoblast fell four percent or more; Anteo, Circadian, Ellex and Starpharma were down three percent or more; Avita, Nanosonics and Prana shed more than two percent; Alchemia, CSL, Osprey, Pharmaxis, Phosphagenics and Sirtex were down more than one percent; with Acrux, Impedimed and Psivida down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense says it will run a small, higher dose trial of ATL1103 for acromegaly, seek early access for ATL1102 for multiple sclerosis and hopes to partner both drugs by July 2015.

In September, Antisense said it found significant dose-related efficacy for ATL1103 in its 26 patient phase II acromegaly trial, and in an investor briefing said that a higher dose for a longer period should be safe and produce greater efficacy (BD: Sep 3, Oct 20, 2014).

Today, the company said that it planned to increase the subcutaneous dose of ATL1103 to 600mg/week compared to the earlier trial's 200mg/week and 400mg/week week doses.

Antisense said that it had applied to conduct a trial of four patients, with ethics committee approval expected by the end of 2014 to start the trial early next year.

The company said that given "the relatively low cost" of the trial, its eligibility for the 45 percent Federal Government Research and Development Tax Incentive and to keep the drug's development on track, it would conduct the trial in parallel with the partnering process to add further value to ATL1103 ahead of the phase III registration trials, which would be conducted with a pharmaceutical partner.

Antisense said that at the same time it was investigating the compassionate use provision of ATL1102 for multiple sclerosis in Europe under an early access program for named patients.

In 2008, Antisense and its then Israeli partner Teva Pharmaceutical reported ATL1102 "significantly reduced disease activity in patients with relapsing-remitting multiple sclerosis" in a 76-patient, randomized, double-blind, placebo-controlled phase IIa study (BD: Jun 30, 2008.

In 2010, Teva handed the drug back to Antisense saying that ATL1102 would "no longer be in line with Teva's preferred product profile". (BD: Mar 24, 2010)

Today, Antisense said that it would seek approval in markets where ATL1102 would qualify for use on compassionate use and named patient grounds including those where it could charge for drug access resulting in a possible early income stream.

Antisense said it had identified a potential existing source of ATL1102 for use in an early access program and assuming the material would be available and suitable for use there would be sufficient quantities for one year's treatment for about 200 patients.

The company said it was "in discussions with an experienced European based group to set up and run the program".

Antisense chief executive officer Mark Diamond told Biotech Daily that if the European program was successful the company would seek to expand to other markets where it could receive payment from an early access program.

The company said that pricing for the program would be determined with the insight of the European firm, but said that as "a point of reference" the hospital price of Tysabri for multiple sclerosis in Europe ranged from $25,000 to $33,000 per patient a year.

Antisense said that it planned to conduct a phase IIb trial of ATL1102 for multiple sclerosis with a funding and development partner.

The company said that it was working with US based advisory firm Destum Partners through the partnering process which was "well advanced with the disclosure of confidential information to a number of interested parties who are actively undertaking partnering-related due diligence".

Antisense said that the process of engagement with pharmaceutical partners "takes time", but with Destum, it was aiming to complete the process and progress into the definitive agreement stage within the next three to six months, although any current partnering interaction could lead to a formal offer at any point in time.

Antisense fell one sense or 10.5 percent to 8.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says that Siemens Healthcare Diagnostics has received Conformité Européenne (CE) mark approval for the Xprecia Stride Coagulation Analyzer.

Universal Biosensors said that the collaboration with Siemens had produced "the first point-of-care coagulation analyzer".

The company said the Xprecia prothrombin time, international normalized ratio (PT-INR) testing system was used to monitor the application of the anti-coagulant therapy, Warfarin.

Universal Biosensors said it would exclusively manufacture PT-INR strips for Siemens at its plant in Rowville, Victoria.

The company said that the CE mark approval followed the receipt of two commercial orders from Siemens for the production and supply of PT-INR test strips and was the final step prior to product launch in Europe.

Universal Biosensors said that about 10 million patients globally were taking Warfarin and were prescribed the drug for a variety of reasons, including the treatment of blood clots in the veins or heart conditions which increased the likelihood of a potentially life-threatening clot forming.

The company said that patients on Warfarin required frequent testing of the clotting tendency of their blood and PT-INR testing allowed physicians to adjust patient doses for diet and lifestyle changes.

Universal Biosensors said that the worldwide point-of-care coagulation testing market was estimated at around $US1.0 billion in 2014 and was forecast to grow by nine percent a year to $US1.4 billion by 2018, with PT-INR testing about 65 percent of the testing market.

Universal Biosensors chief executive officer Paul Wright said that CE marking was "an important step prior to the market launch of this exciting new coagulation testing product developed in partnership with Siemens".

"We are looking forward to the launch of this new device and continue to work with Siemens to bring powerful and innovative systems to point-of-care testing," Mr Wright said.

Universal Biosensors was up two cents or 12.9 percent to 17.5 cents with 1.4 million shares traded.

GI DYNAMICS

GI Dynamics says that chief financial officer, secretary and treasurer Robert Crane had agreed to his "separation" effective immediately as part of a broader company restructure.

GI Dynamics said that Mr Crane would separate subject to the notice period provided in his employment agreement.

The company said the restructure involved a reduction of about 10 percent of staff.

GI Dynamics chief executive officer Michael Dale said that the restructure was "based on a re-evaluation of our corporate strategy and the skills and resources we believe will be required by the company in the future".

"I want to thank Bob and the other affected employees for their contributions to GI Dynamics over the past several years," Mr Dale said. "Under Bob's leadership, the company has built a solid financial organization, which will serve us well going forward."

"We will not immediately be replacing Bob's position as existing finance team members will assume his responsibilities," Mr Dale said.

Mr Dale said that with the board he was "continuing to work to develop a strategic plan for the company in order to fully capitalize on the opportunities before us and fulfill our mission".

GI Dynamics fell two cents or seven percent to 26.5 cents with 1.1 million shares traded.

IMUGENE

Imugene says its one cent a share plan has raised $833,500 and with a subsequent placement raising $500,000 it had raised a total of $3,583,500.
Last month, Imugene said a placement had raised $2.25 million (BD: Nov 13, 2014).
The company said that the additional placement of 50,000,000 shares was made to sophisticated investors of Forrest Capital at one cent a share and was put in place following unexpected demand in the initial placement.
Imugene said the funds would support the manufacture of cancer treatment HER-Vaxx including initiation of clinical trials, the company's phase Ib/II clinical trial in patients with metastatic gastric cancer, preclinical work, corporate costs, intellectual property prosecution and general corporate purposes.
Imugene was unchanged at 1.1 cents.

BONE MEDICAL

Bone says BN006 "has not been sufficiently advanced by these new results to justify continuing development".
Bone said that a Proxima Concepts report showed that on only one of the important measures of efficacy and at one dose did BN006 appear to be close in its effects to the market leaders.
Bone said that Proxima was the inventor and patent holder of BN006 and in an animal rheumatoid arthritis model, investigated its ability to achieve advantageous therapeutic effects across a broader dose range compared with market-leading treatments.
The company said that a number of other BN006 product parameters remained unclear following completion of the experimental evaluation budgeted under the company's January 2014 recapitalization plan and that further data on the ability to administer the product orally indicated that this could not be accomplished without more extensive formulation work.
Bone said the underlying mechanism of action remained undetermined following inconclusive laboratory work carried-out earlier this year.
In November, Bone said it would "terminate the agreements with the Proxima Group" following an evaluation of its technologies and near completion of product development studies (BD: Nov 19, 2014).
Bone said it "has concluded that it is not in the commercial interests of the company or its shareholders to continue with the Proxima Group under the current structure".
Bone said at that time that it was in discussions with one of the Group's subsidiary companies to obtain some interest in BN006 pending the outcome of the current studies and the parties agreeing terms acceptable to Bone.
Bone said that the Capthymone oral treatment for osteoporosis had not generated meaningful parathyroid hormone levels in blood, when comparing parathyroid hormone levels from different doses of its oral parathyroid hormone Capthymone against the commercially available injectable Forteo.
Bone was created by investors in Proxima and licenced Capthymone and BN006 compounds from four subsidiary companies within the Proxima Group and had the use of the Proxima Laboratory and Research Services laboratory.
Proxima co-founder and research director Dr Roger New was formerly Bone's chairman (BD: Jul 11, Sep 22, 2011; Jan 29, Apr 4, May 12, Jun 20, 2014).
Bone said it would "focus on identifying new technology opportunities both in health science and other sectors".
Bone fell 0.1 cents or 16.7 percent to 0.5 cents with 6.3 million shares traded.

ALCHEMIA

Alchemia says it has appointed the New York-based Evolution Life Science Partners "to assist with the execution of a strategic transaction" for its VAST drug discovery platform.
Alchemia's media release was not clear whether the company wanted to sell the versatile assembly on stable templates (VAST) drug discovery platform or to gain further licence deals from its discoveries.
In October, Alchemia's share price fell more than 80 percent on news that its phase III trial of hyaluronic acid-irinotecan as part of the Folfiri regime showed no benefit for metastatic colorectal cancer (BD: Oct 27, 2014).
Alchemia executive director Dr Tracie Ramsdale said that the company was undertaking "a comprehensive strategic review" and the appointment of Evolution "to specifically secure an investment and/or partner to accelerate the development of VAST [was] representative of our ongoing effort to evaluate and prioritize the company's assets and operations".
Alchemia said the VAST drug discovery platform provided access to three-dimensional molecular diversity and had success in finding hits for a range of target types confirming its applicability to drug discovery.
The company said that in 2013, it signed a multi-target drug discovery collaboration with Astrazeneca AB and was eligible to receive up to $240 million in milestone payments, plus research and development expenditure and royalty payments (BD: Apr 23, 2013).
"Evolution is an ideal partner for this mandate as the firm has proven business development expertise having delivered global pharma and biotech licensing, partnering and [merger and acquisition] transactions for opportunities such as the VAST technology," Dr Ramsdale said. "[We] expect to provide a full update on the company's strategic review in January 2015."
Alchemia fell 0.1 cents or 1.2 percent to 8.5 cents.

COCHLEAR

Cochlear says it has appointed Glen Boreham and Alison Deans as independent non-executive directors effective from January 1, 2015.
Cochlear said that Mr Boreham had held senior executive roles, most recently as IBM Australia and New Zealand managing director until his resignation in 2011.
The company said that Mr Boreham was currently the University of Technology Sydney's industry advisory board chair.
Cochlear said Mr Boreham held a Bachelor of Economics from the University of Sydney.
The company said that Ms Deans had more than 20 years' experience in senior management and consulting roles including electronic commerce.
Cochlear said Ms Deans had been a consultant with McKinsey and held senior roles including chief executive of Ecorp, Hoyts Cinemas and Ebay Australia and New Zealand.
The company said that most recently, Ms Deans was the chief executive officer of technology-based investment company Netus and she was currently a director of Westpac Banking Corp, Insurance Australia Group and Kikki K Holdings.
The company said that Ms Deans held a Bachelor in Natural Sciences from Cambridge University UK and a Masters of Business Administration from California's Stanford Graduate School of Business.
Cochlear was up 87 cents or 1.2 percent to $73.77 with 430,751 shares traded.