Biotech Daily

Wednesday April 15, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 24%, GI DYNAMICS DOWN 18%**

*** CELLMID TRIAL: 'ÉVOLIS ONE REDUCES HAIR LOSS'**

*** POLAND APPROVES PSIVIDA ILUVIEN**

*** BLUECHIIP RAISES $1m**

*** PHARMAUST TAKES PPL-1 TO HIGHER DOSE, CAPSULE FORMULATION**

*** NEW JERSEY'S SABBY CEASES SUBSTANTIAL IN VIRALYTICS**

*** SOLAGRAN CLAIMS US PATENT FOR ROPREN, PRENOLS**

MARKET REPORT

The Australian stock market fell 0.64 percent on Wednesday April 15, 2015 with the S&P ASX 200 down 38.2 points to 5,908.4 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Cellmid was the best, was up half a cent or 23.8 percent to 2.6 cents with 29.3 million shares traded followed by Antisense up 10.5 percent to 10.5 cents with 107,691 shares traded.

Actinogen, Pharmaxis and Viralytics climbed more than seven percent; Benitec was up five percent; Admedus and Atcor were up more than four percent; Biotron and Impedimed were up more than three percent; Nanosonics rose 2.05 percent; with Acrux up 1.2 percent.

GI Dynamics led the falls for the second day in a row, down 2.5 cents or 17.9 percent to 11.5 cents with 4.1 million shares traded, followed by yesterday's best, Compumedics, retreating 10 percent to 22.5 cents with 587,781 shares traded.

Optiscan lost 6.25 percent; Mesoblast and Sirtex fell more than five percent; Tissue Therapies fell 4.8 percent; Oncosil and Prima were down more than three percent; Bionomics, Clinuvel, Medical Developments and Starpharma shed two percent or more; Anteo, Avita, IDT, Resmed and Universal Biosensors were down more than one percent; with Cochlear and CSL down by less than one percent.

CELLMID

Cellmid says a 32-patient study of its Évolis One formulation showed a “statistically significant 80.2 percent reduction in hair loss over 112 days with twice daily use”.
Cellmid said that the 16-week, independently-conducted, randomized, blinded and placebo-controlled trial of its FGF5 inhibitor Évolis One used a gravimetric analysis to establish statistical significance, in which a trained technician combed each subject’s hair 20 times employing a standardized technique to capture the fall-off, with recovery aggregates weighed to establish hair loss reduction patterns if any.
The company said that hair differentiation, or anagen/telogen ratio, a measure of growing versus resting hair follicles, improved with an increase of 44.2 percent in growing follicles during the same period, as analyzed by the Van Scott hair-pluck method.
Cellmid said that hair release and recovery, an overall improvement in hair quality and volume, was quantified by Photogrammetrix3 measurements and showed an improvement by a statistically significant 143.3 percent.
The company said the trial objectives included quantitative assessment of hair loss, hair release and recovery and hair differentiation.
Cellmid said that male and female patients had patterned baldness, were otherwise in general good health and within the healthy weight range, aged 31 to 55 years.
The company said that the trial was conducted by the New York-based AMA Laboratories and followed a 51-subject repeat insult patch test to assess safety by evaluating skin irritation and sensitization, which resulted in a zero adverse event report.
Cellmid chief executive officer Maria Halasz said that “in addition to the hair count and hair loss measurements the photographs taken during the Photogrammetrix evaluation demonstrate visible improvement in overall hair quality and volume”.
“As this product has active ingredients subject to Cellmid’s recently filed patent application, the results give us multiple opportunities to commercialize this valuable asset,” Ms Halasz said.
Cellmid product development head Darren Jones said the results were “very exciting and valuable ... [and were] expected to support stronger clinical hair growth claims of this proprietary product”.
“FGF5 is well-recognized as the ultimate controller of hair loss,” Mr Jones said.
“We are excited to be the first on the market with a clinically validated product range addressing FGF5,” Mr Jones said.
Cellmid was up half a cent or 23.8 percent to 2.6 cents with 29.3 million shares traded.

PSIVIDA

Psivida says that Polish approval for Iluvien for diabetic macular oedema is its seventeenth European approval.
Psivida said that the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland granted marketing authorization for Iluvien for the treatment of vision impairment associated with diabetic macular oedema considered insufficiently responsive to available therapies.
The company said that Iluvien was on sale through its licencing partner Alimera Sciences in the US, UK, Germany and Portugal.
Psivida said it was entitled to 20 percent of net profits of Iluvien sales on a country-by-country, quarter-by-quarter basis.
Psivida was untraded at $5.50.

BLUECHIIP

Bluechiip says it has raised $1,000,000 at 4.5 cents a share in a placement to sophisticated and professional investors.
Bluechiip said the funds would be used predominately for working capital to commercialize its wireless medical tracking tag system.
The company said that non-executive directors Iain Kirkwood and Michael Ohanessian to participated in the placement to acquire a total of $81,500 in shares, pending shareholder approval.
Bluechiip said that Halcyon Corporate was the lead manager for the placement.
Bluechiip was unchanged at 5.5 cents with 1.4 million shares traded.

PHARMAUST

Pharmaust says it will proceed to a higher dose in its phase I/II dose escalation trial of PPL-1 for cancer and will develop a tasteless capsule formulations for humans.
Pharmaust began the human trial last year in parallel with a canine cancer trial which was delayed while a capsule version was developed to combat the issue of palatability for dogs (BD: Aug 7, Sep 9, 2014).
The company said the trial was being conducted at the Royal Adelaide Hospital and it had received ethics and trial safety approval to escalate the dose of PPL-1 from the 5mg/kg lowest dose to the next cohort dose of 25mg/kg.
Pharmaust said the Hospital's trial safety committee considered the "low and acceptable adverse event profile of PPL-1 at the lowest dose ... and the demonstration of inhibitory activity on a key tumor marker".
The company said that the trial safety committee observed taste and palatability issues with PPL-1.
Pharmaust said that as the quantity of drug being consumed orally increased with escalating doses, "there may be some challenges in patients tolerating the treatment due to the taste".
Pharmaust said it would "commit to developing a tasteless capsule formulation of PPL-1 to facilitate higher doses in both the present and future trials".
Pharmaust climbed as much as 0.2 cents or 16.7 percent to 1.4 cents before closing unchanged at 1.2 cents with 11.2 million shares traded.

VIRALYTICS

The New Jersey-based Sabby Healthcare Volatility Master fund says it has ceased its substantial holding in Viralytics, selling 24,721 shares for $11,626 or 47.0 cents a share.
Last year, Sabby became substantial in the Viralytics $27 million placement at 28 cents a share with a holding of 10,671,786 shares or 5.8 percent (BD: Mar 13, 14, 2014).
Today, Sabby said it sold the 24,721 shares on April 14, 2015 and continued to hold 9,197,797 shares, implying it had sold a total of 1,473,989 shares but not disclose the price or dates it sold the remaining 1,449,268 shares.
Viralytics was up 3.5 cents or 7.3 percent to 51.5 cents with 1.1 million shares traded.

SOLAGRAN

Solagran says it has a US patent covering its “Ropren and other prenol formulations ... for certain disease types caused by excessive activity of monoamine oxidase enzymes.
Solagran said that monoamine oxidases were a family of enzymes involved in the breakdown of neurotransmitters and the patent, entitled ‘Medicinal agent for treating patients suffering from diseases caused by the monoaminooxidase excessive activity and a method for treating patients suffering from diseases caused by monoaminooxidase excessive activity’ provided exclusivity for the company’s methods for treating related diseases, which could include Alzheimer’s, Parkinson or Huntington diseases and also for treating dependency on agents such as alcohol, nicotine and other addictive drugs.
The company said that corresponding had been granted in Australia and Russia, and filed in other selected jurisdictions.
Solagran has been attempting to commercialize Ropren and its range of Bioeffectives derived from pine needles since listing on the ASX in December 2002 and describes itself as a “healthcare and wellness company” based in South Melbourne and was developing a treatment for liver cancer, Alzheimer’s disease and a raft of other indications based on Ropren and the Bioeffectives (BD: Feb 25, 2009; Feb 5, 2010).
Despite claiming large contracts and building a manufacturing plant, Solagran was twice suspended by the ASX for failing to lodge accounts (BD: Mar 1, 2011; Mar 9, 2012).
In February 2012, Solagran said it would form a joint venture with Russia’s Art Life to develop and manufacture food additive products using its conifer needle extract Bioeffectives and quoted Art Life founder Prof Alexander Avstrievskih “forecasting revenues in the order of $US100 million [$A93.6 million] for 2012”.
Despite Solagran personnel joining Bioprospect (now Medibio), an agreement between the two companies on Bioeffectives was terminated with Bioprospect alleging it could source the pine needle extract cheaper elsewhere and the two companies were involved in litigation (BD: Jun 28, Aug 5, Sep 20, Oct 27, 2010).
Solagran remained suspended at 3.9 cents.