Biotech Daily

Monday September 24, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 12%, CELLMID DOWN 12%**

*** VAXINE'S $3.4m FOR BIOXYNE'S PROBIOTEC, NEW HI-164OV TRIAL**

*** GSK COMPETITOR HITS ALCHEMIA FONDAPARINUX 1st PROFIT**

*** OPTISCAN EARNS $746k ZEISS NEUROSURGERY MILESTONES**

*** USCOM 'ROLE IN CANCER TREATMENT'**

*** ST VINCENT'S, MACQUARIE ADOPT GI DYNAMICS ENDOBARRIER**

*** ISONEA REQUESTS CAPITAL RAISING TRADING HALT**

*** MAYNE REVIEWING OPTIONS, MAY OR MAY NOT RAISE CAPITAL**

*** BURNET'S PROF GILDA TACHEDJIAN WINS FRANK FENNER GONG**

MARKET REPORT

The Australian stock market fell 0.52 percent on Monday September 24, 2012 with the S&P ASX 200 down 22.8 points to 4,385.5 points.

Six of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and nine were untraded.

Optiscan was the best, up one cent or 11.8 percent to 9.5 cents, with 68,000 shares traded.

Neuren and Prima climbed eight percent or more; Bionomics was up four percent; Clinuvel rose 2.6 percent; CSL was up 1.3 percent; with Sirtex up 0.55 percent.

Cellmid led the falls, down 0.2 cents or 11.8 percent to 1.5 cents with 527,500 shares traded, followed by Alchemia down as much as 23.4 percent to 41 cents before closing down 10.3 percent at 48 cents with two million shares traded and Prana down 10 percent to 22.5 cents with 1.1 million shares traded.

Benitec lost 6.7 percent; Viralytics fell 5.9 percent; Patrys, Phylogica and Tissue Therapies were down more than three percent; Acrux, Mesoblast, QRX and Reva shed more than two percent; Biota, Living Cell and Pharmaxis and were down more than one percent; with Cochlear and Resmed down by less than one percent.

BIOXYNE

Bioxyne says Vaxine will buy its probiotics business for $3.4 million and the two companies will redo the phase II HI-164OV chronic obstructive pulmonary disease trial.

Earlier this year Bioxyne lost 87.5 percent of its share price on the release of results from a 320-patient phase IIb trial showing that HI-164OV had not met its exacerbations of chronic obstructive pulmonary disease endpoints (BD: June 28, 2012).

More recently there have been two meeting requests to appoint new directors with a meeting called for October 30, 2012 (BD: Sep 20, 2012).

Today Bioxyne said it had a heads of agreement with the Adelaide-based private vaccine developer Vaxine for funding to support “further investigation of the results from its recent phase II trial”.

The company said that retrospective analyses were supportive of a potential clinical benefit of its HI-164OV therapy and “a new and highly focused phase II study in partnership with Vaxine [would] further investigate the hypotheses resulting from retrospective analyses of the earlier studies”.

Bioxyne said the agreement required the execution of other documents by November 1, 2012, and, on execution it would raise about $3.4 million from the sale of its probiotics business and sale of equity to Vaxine, but did not disclose how much would be cash.

The company said the new study would be run collaboratively with Vaxine, which had experience in large scale international vaccine trials.

Bioxyne chief executive officer David Radford said that “several international pharmaceutical groups have expressed interest in the data from our recent phase II study and the clinical signal demonstrated in enriched patient populations [and] we are continuing to explore opportunities for a co-investor in the proposed study”.

“This agreement with Vaxine will allow us to cost-effectively explore and better understand the major hypotheses arising from the range of clinical studies while retaining future growth opportunities,” Mr Radford said.

Bioxyne said investor would vote on the issue of equity to Vaxine on October 30, 2012.

Vaxine founder and research director Prof Nikolai Petrovsky said that data on HI-164OV showed the therapy had “potential for a clearly defined group of … patients, and look forward to assisting the company complete this study”.

Bioxyne said that Vaxine was creating vaccines targeting a range of unmet medical needs and had completed six phase I and phase II clinical trials for four different vaccine products, including hepatitis B, seasonal influenza, pandemic influenza and insect bite allergy and held a multimillion dollar vaccine development contract with the US Department of Health and Human Services and National Institutes of Health.

Prof Petrovsky, a professor of medicine at Flinders University, told Biotech Daily that the company had won about $US12.5 million in US grants over eight years and had “a substantial amount” of cash.

Prof Petrovsky said the probiotec space was gaining attention in the scientific literature and Vaxine subsidiary Zinulin was already selling the pre-probiotic Inulin as a soluble dietary fibre to correct constipation and increase the growth of probiotics to displace Escherichia coli and other potentially damaging gastro-intestinal bugs.

“We can inject a lot of value,” Prof Petrovsky said. “We have good connections in Japan and the US.”

Bioxyne said that in 2009 Vaxine developed of the world’s first ‘swine flu’ pandemic vaccine to enter the clinic.

Bioxyne said its cash position has been helped by the receipt of a Federal Government research and development tax credit of $1.5 million.

Bioxyne was untraded at 2.5 cents.

ALCHEMIA

Alchemia says it has earned its first profit of $125,535 from generic fondaparinux, but competition from Glaxosmithkline's authorized generic will force cost reductions.

Alchemia said that its synthetic heparin fondaparinux was launched in the US in July 2011 by partner Dr Reddy's Laboratories and the inaugural profit for the three months to June 30, 2012 marked "the start of the profitability of the product and reflects the fact that the development costs under the … agreement were repaid towards the end of the quarter, after which profit has been divided equally between the partners".

Alchemia chief executive officer Dr Pete Smith told Biotech Daily said that the profit "came late in the quarter and we are expecting much more in the coming quarter".

Alchemia said that in the year to June 30, 2012, Dr Reddy's had net fondaparinux sales of $33 million, predominantly from retail sales, where the product had 41 percent market share at the end of June 2012, net of charge-backs, discounts and rebates reflecting increased price competition due to the authorized generic.

Alchemia said that to counter authorized generic price pressure, it and Dr Reddy's had invested in further process and production improvement, to reduce the cost of the active pharmaceutical ingredient and increase the profitability of fondaparinux.

Alchemia said that Dr Redddy's agreed the $10 million in costs would be born equally by both companies, with Alchemia's share deducted from net quarterly profit receipts over the next 10 quarters at $500,000 per quarter.

The company said that the benefits of the investment were expected to flow through into increased profits from the three months to December 31, 2012.

Alchemia said the manufacturing cost reduction was expected to assist in maximizing profits in non-US markets where the selling price of fondaparinux was significantly lower.

The company said that the investments meant that, despite the extra cost of research and development, anticipated profits to Alchemia arising from sales of fondaparinux in the US were in line with expectations.

Dr Smith said the Glaxosmithkline authorized generic "delayed the point at which the product became profitable resulting in a more modest than expected profit for the quarter ending June 30, 2012, but we expect the significant reduction in API cost should ensure that the profitability of the product will be in line with our expectations".

"We can also reaffirm that we are unaware of any other filings for approval of another generic, supporting the long term ability of this product to generate value for both partners," Dr Smith said.

Alchemia fell 5.5 cents or 10.28 percent to 48 cents with two million shares traded.

OPTISCAN

Optiscan says it will earn EUR600,000 ($A745,751) in two milestone payments from its collaboration with Zeiss for its miniaturized confocal microscopes for neurosurgery.

Optiscan said that due to the successful evolution of the collaboration, Zeiss agreed that significant late stage milestones could be paid, with the first EUR300,000 payment due on September 25, 2012 and the second EUR300,000 payment after delivery of specific components, expected to take place by March 31, 2013.

The company said that its recent $1 million capital raising, purchase orders, grants and the milestones combined "to form a strong cash flow profile this financial year".

Optiscan said that "actual and virtually certain" cash inflows for the financial year to date were more than $3 million, which was "a very favorable foundation leading in to commercial sales to Zeiss".

Optiscan was up one cent or 11.8 percent to 9.5 cents.

USCOM

Uscom says that independent research confirms the effectiveness of its ultra sonic cardiac output monitoring during cancer treatment.
Uscom said that research entitled 'Anthracycline-Induced Cardiotoxicity: Cardiac Monitoring by Continuous Wave-Doppler Ultrasound Cardiac Output Monitoring and Correlation to Echocardiography' from the Ludwig-Maximilians University of Munich, Germany, was published in the cancer journal Onkologie.
An abstract is at: http://content.karger.com/ProdukteDB/produkte.asp?Doi=338335.
The company said the research team studied 50 patients being treated for various kinds of cancers with drugs which could be complicated by cardiac damage and compared results using the current method with those from Uscom and found that "Combining … Uscom and serum biomarkers is feasible for monitoring the immediate and chronic haemodynamic changes during an anthracycline based regimen."
Uscom said the research recommended further study of its monitor in haematology and oncology.
Uscom said that a number of drugs can be used to reduce the growth of the cancers, but those drugs could damage the heart, so early detection of changes in heart function allowed changes in treatment to limit the cardiac complications.
The company said the study demonstrated Uscom was cost-effective for detecting these changes and useful for monitoring the patients.
"This is further evidence of the platform nature of the Uscom technology and confirms the potentially community wide usefulness of Uscom monitoring," Mr Phillips said.
Uscom was unchanged at 17 cents.

GI DYNAMICS

GI Dynamics says that Sydney's St Vincent's Clinic and Macquarie University Hospital have adopted its Endobarrier for obesity and type 2 diabetes.
GI Dynamics said that the St Vincent's Clinic was part of the greater St Vincent's Health Care campus, comprising St Vincent's Public and St Vincent's Private Hospitals.
GI Dynamics chief executive officer Stuart Randle said that St Vincent's gastrointestinal, bariatric and general surgeon Prof Reginald Lord was leading the team which would be inserting the Endobarriers.
Prof Lord said that St Vincent's "has always been at the forefront of scientific discovery, medical innovation and patient care, so we are pleased to be able to add this innovative procedure to our repertoire of obesity and diabetes solutions".
"We also offer Endobarrier therapy through the new Macquarie University Hospital, which is possibly the most technologically advanced hospital in Australia," Prof Lord said.
"Its location in Sydney's North West means that we are able to provide this treatment for patients across the broader Sydney metropolitan area," Prof Lord said.
GI Dynamics said the Endobarrier was delivered endoscopically, or through the mouth, during a brief, non-surgical procedure and was a thin, flexible, tube-shaped liner that formed a physical barrier between food and a portion of the intestinal wall.
The company said the device began working immediately and had been shown to lower HbA1c or blood glucose levels, achieve weight loss of about 20 percent and improve other metabolic functions including cholesterol, blood pressure and triglycerides within one year.
GI Dynamics said there were estimated to be more than 3.5 million Australian adults with either diabetes or pre-diabetes; type 2 diabetes cost the country about $3 billion a year; and obesity had overtaken smoking as the leading cause of premature death and illness.
GI Dynamics was up two cents or 2.9 percent to 71 cents.

ISONEA

Isonea has requested a trading halt pending an announcement “in relation to a proposed capital raising”.
Trading will resume on September 26, 2012 or on an earlier announcement.
Isonea last traded at 5.4 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it is “aware of media speculation in relation to a capital raising” which it could be considering.
Mayne Pharma said that it was “reviewing a number of strategic options to grow the business and is considering a capital raising as part of this strategy, which is preliminary, uncertain and incomplete”.
Mayne Pharma fell 1.5 cents or 3.7 percent to 39.5 cents.

THE BURNET INSTITUTE

The Burnet Institute says Prof Gilda Tachedjian has won the Australian Society for Microbiology’s 2012 Frank Fenner Award for her work on retroviral biology and antivirals.
The Institute said that along with a cash prize of $1,000, Prof Tachedjian will give the Australian Society for Microbiology Fenner Oration in Adelaide next year.
The Institute said that the award recognized distinguished contributions in any area of Australian research in microbiology by scientists in a formative stage of their career.
The Burnet Institute said that Prof Tachedjian who led a large team of researchers in her laboratory.
“I am honored to be the 2012 recipient of the Australian Society for Microbiology Frank Fenner Award named after an eminent scientist who was instrumental in the eradication of smallpox, a remarkable achievement,” Prof Tachedjian said.
“Like smallpox, there is a concerted effort to eradicate HIV, which currently affects an estimated 33 million individuals worldwide,” Prof Tachedjian said.
“It is pleasing that the contributions made by my laboratory in the last 15 years in understanding how HIV reproduces in target cells, how this virus becomes resistant to drugs used in the clinic, and more recently, studies on microbicides that can be used by women to prevent HIV and other sexually transmitted infections have been recognized by the [Australian Society for Microbiology],” Prof Tachedjian said.