Biotech Daily

Friday April 13, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 22%, GENERA DOWN 9%**

*** BIONICHE CALMS INVESTORS WITH REVENUE, NEW PROJECTS**

*** ALCHEMIA TREATS 53 CANCER PATIENTS, AWAITS SAFETY REVIEW**

*** PRIMA TO LIST ON NASDAQ NEXT WEEK**

*** GENETIC TECHNOLOGIES' IMMUNAID RAISES $1m**

*** BIOXYNE CONFIRMS NAME CHANGE, PHASE IIb COPD TRIAL ON-TRACK**

*** UBS AG FALLS BELOW 5% OF PHARMAXIS**

*** EVADO EVALUATES UWS COMPLEMENTARY MEDICINE**

*** FERMISCAN DROPS BIOTECH FOR RESOURCES, NAME CHANGE**

MARKET REPORT

The Australian stock market was up 1.0 percent on Friday April 13, 2012 with the S&P ASX 200 up 42.7 points to 4,323.3 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, five traded unchanged and seven were untraded. All three Big Caps were up.

Prima was the best, up five cents or 22.2 percent to 27.5 cents with 39.8 million shares traded, followed by Cellmid up 15.4 percent to 1.5 cents with 623,485 shares traded.

Patrys climbed 10 percent; Prana was up 6.45 percent; both Benitec and Ellex were up 5.6 percent; Neuren and Phosphagenics were up more than four percent; Clinuvel and Phylogica rose more than two percent; Acrux, Alchemia, CSL, Nanosonics and QRX were up more than one percent; with Biota, Cochlear, Mesoblast, Resmed, Sirtex and Starpharma up by less than one percent.

Genera led the falls, down two cents or 9.1 percent to 20 cents, with 48,654 shares traded.

Impedimed lost 6.7 percent; Sunshine Heart was down 3.3 percent; Avita and Tissue Therapies shed more than two percent; Bionomics, Genetic Technologies and Universal Biosensors were down more than one percent.

BIONICHE

Bioniche executives are in Australian to reassure investors that despite the company's share price fall, it has increased revenue and several projects underway.

Bioniche chairman and chief executive officer Graeme McRae told Biotech Daily that since listing at $1.50 the company's share price had fallen to 56 cents, but the company was expanding manufacturing capability for its Urocidin compound in phase III bladder cancer trials from 30,000 doses a year to 90,000 doses a year (BD: Nov 30, 2010).

"There are a lot of good things we can't speak about that are under confidentiality," Mr McRae said.

Mr McRae said that Endo Pharmaceuticals had paid Bioniche a total of $US38 million in licence fees and milestone payments, but Endo had total control of the phase III trial and had not released any information other than that 73 of 120 sites had been activated in the 450 patient trial.

Mr McRae said that despite Endo's orders for Urocidin for the trial, his company did not know how many patients had been recruited or treated.

But Mr McRae said that given the positive results in the company's earlier 129-patient trial, Bioniche had taken the decision to upgrade manufacturing to 90,000 doses a year, this year, with plans to build a one million dose per year plant, once Endo completed its trial and filings.

Mr McRae said that 25 percent of patients in the earlier single-arm trial were cancer free at 12 months.

He said the phase III Endo trial was a comparative trial against the standard treatment, mitomycin C.

Mr McRae said that the Urocidin's underlying technology, a mycobacteria cell wall compound was being used in canine cancers with a product expected to be launched in the US and Canada in July 2012.

Mr McRae said dog cancers were usually treated with human chemotherapy agents which had similar toxic side effects in animals as they did in humans.

He said a second compound Sin Susto, which was derived from a South American plant had been licenced from the University of Ottawa and was being developed as an anti-anxiety drug for dogs, horses and potentially humans.

Mr McRae said that Sin Susto or "without fear" appeared to have no side effects and was not addictive.

He said the company would report animal health revenue figures in May and expected an increase for both the current quarter and the year-to-date.

He said that Bioniche had the rights to the embryo transfer hormone, follicle stimulating hormone, used to ensure animal breeding and had 70 percent of the world market for the drug.

But he said that the seven major multinational companies in the veterinary marklet controlled 70 percent of that market.

Mr McRae said that he would be meeting with the Australian Veterinary Association in Sydney next week, both to introduce Bioniche, and to discuss the lack of innovation in animal health products caused by the domination of the industry by major companies.

Bioniche was untraded at 56 cents.

ALCHEMIA

Alchemia says safety data is being collated from the first 20 patients in its phase III trial of hyaluronic acid irinotecan for metastatic colorectal cancer.

Alchemia said the data would be reviewed by an independent data safety and monitoring board with a response expected “in the coming weeks”.

The company said that a total of 53 of the intended 390 patients had been recruited and were being treated, pending any findings from the data safety and monitoring board.

Alchemia said that hyaluronic acid (HA) irinotecan was a new formulation using its Hyact technology to target the widely used chemotherapy drug irinotecan directly to cancer cells.

Alchemia said that the 390-patient phase III Australian and European trial was designed to compare the effectiveness and safety of HA-Irinotecan with irinotecan when administered as part of the standard regimen commonly used to treat metastatic colorectal cancer patients who have failed at least one previous line of therapy.

The company said that the primary objective was to demonstrate that HA-Irinotecan provided superior efficacy as indicated by an increased period of progression-free survival.

Alchemia said the trial was being conducted at 57 sites in seven countries including Australia, and Eastern and Western Europe, with 45 sites in the seven countries having been activated and evaluating eligible patients.

The company said that this week some patients received their sixth cycle of treatment or 12 doses of drug and only three patients had discontinued treatment - all due to disease progression.

Alchemia said that the trial was expected to take about 12 months to recruit the required 390 patients and the primary endpoint would be reached when 350 patients experienced disease progression, expected by October 2013.

Alchemia chief executive officer Dr Peter Smith said the company would “continue to closely manage this important trial to ensure our target for recruitment is met”.

“We believe HA-Irinotecan and, in due course, other Hyact drugs, have the potential to radically improve the existing standard of care for cancer patients,” Dr Smith said.

The company said that a phase II trial of HA-Irinotecan in metastatic colorectal cancer showed a statistically significant increase in progression-free survival compared with irinotecan (5.2 months vs 2.4 months, p = 0.017) with no increase in toxicity.

Alchemia said that both the US Food and Drug Administration and the European Medicines Agency indicated that the successful completion of the single pivotal phase III trial could be sufficient for registration in both the US and Europe.

Alchemia was up one cent or 1.9 percent to 52.5 cents.

PRIMA BIOMED

Prima says it will list on the Nasdaq, trading American depositary receipts (ADRs) under the code PBMD from April 16, 2012.

Prima said it would then have dual listings on both the ASX and Nasdaq with each ADR representing 30 ordinary fully paid Australian shares.

The company said the Nasdaq listing was a level II ADR compliance listing and will be managed by Bank of New York Mellon, which would be its deposit agent for converting shares into ADRs.

Prima said that Deutsche Bank Securities, Noble Financial Capital Markets and Aegis Capital were its market makers for the US.

Prima was up five cents or 22.2 percent to 27.5 cents with 39.8 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says subsidiary Immunaid Pty Ltd has raised $1 million in a private placement from US, European and Australian sophisticated investors.

Genetic Technologies said the finance provided sufficient resources to advance the novel approach to cancer therapy, through the timely reversal of immune system suppression using its on-off technology.

Genetic Technologies said the incoming investors held a 10 percent interest in Immunaid, valuing its stake in its subsidiary at more than $4.5 million.

Genetic Technologies chief executive officer Dr Paul MacLeman said his company chose "not to participate in this placement … to focus on building the Brevagen franchise, managing the [intellectual property] out-licencing program and assessing new business opportunities".

The company said that Immunaid was founded to explore the concept developed by inventor Martin Ashdown that the immune system switches itself "on and off" in a continuous, repeating cycle in patients with chronic infections and diseases, such as HIV; and that timely treatment was critical to support the body's efforts to fight disease.

Genetic Technologies said that subsequently, Mr Ashdown expanded his concept to include cancer, autoimmune and several degenerative diseases.

The company said that Immunaid would use the funds to secure further patents and support human and animal trials directed at validating applications of the technology.

Genetic Technologies fell 0.1 cents or 1.1 percent to 8.9 cents.

BIOXYNE

Bioxyne has confirmed the formal name change from Probiomics following the reverse takeover by Hunter Immunology last week.

Bioxyne chief executive officer David Radford said the company would commercialize its therapy for chronic obstructive pulmonary disease, including emphysema and bronchitis.

"The name change comes at a time when our focus is moving away from research and development to actively seeking to commercialize our first therapeutic asset currently known as HI-164OV," Mr Radford said.

Mr Radford said Bioxyne was on-track for the planned mid-year release of data from a 320 patient clinical trial of HI-164OV.

Mr Radford said that a clinically meaningful result demonstrating efficacy in patients with chronic obstructive pulmonary disease (COPD) would "position our company as a potential partner or acquisition target for a number of multinational pharmaceutical companies seeking to expand their portfolios in respiratory therapy markets".

Mr Radford said there was no cure for COPD, but reducing hospital admissions was crucial and preventing exacerbations was the main focus of therapy.

"A reduction of just 10 percent in the number of patients readmitted to hospital for treatment would be considered a positive result and would potentially have a meaningful impact on the cost of healthcare worldwide to treat COPD, which is currently estimated to cost the US healthcare system $US29 billion every year in direct costs," Mr Radford said.

Bioxyne said that a small phase IIa study in severe COPD patients showed that HI-164OV therapy decreased hospitalization rates while reducing the use of steroids, antibiotics and bronchodilators and that there were also large reductions in the use of corticosteroids and antibiotics for treating exacerbations.

Bioxyne said that the protocol of the current phase IIb study was designed to build on data provided from the phase IIa study and provide statistical validation of previous results.

Bioxyne fell one cent or 5.3 percent to 18 cents.

PHARMAXIS

UBS AG and related bodies corporate have ceased their substantial shareholding in Pharmaxis with “stock returned” under a prime broker lending agreement.
The substantial shareholder notice said that 456,274 shares were described as “stock returned” for no fee, while 333 shares were sold for $451 or $1.354 a share and 208,825 shares were bought for $282,074 or $1.351 a share.
On April 11, the Hong Kong-filed initial substantial shareholder notice said the London UK and Sydney Australia branches were fund managers, beneficial owners and acting as prime brokers in relation to the shares and had become substantial with the acquisition of 15,307,015 shares or 5.00 percent (BD: Apr 11, 2012).
Pharmaxis fell half a cent or 0.4 percent to $1.315.

EVADO

The University of Western Sydney’s Centre for Complementary Medicine Research says it is using Evado’s clinical software platform for its clinical trials in complementary medicine.
The Centre for Complementary Medicine Research said the contract with Evado was for a multi-trial server for three years.
A media release from Evado said the Centre would use its software to determine scientific evidence on the use of complementary medicine in health services.
Evado said the Centre was “recognized as Australia’s leading researchers into traditional Chinese medicine”.
The Centre’s research program coordinator Ros Priest said that Evado “offered excellent support at the various stages of the development and implementation: and an infrastructure grant from the University of Western Sydney funded the implementation of the Evado system.
The media release said that the Evado platform would enable the University of Western Sydney to support an unlimited number of multi-site non-commercial research trials.
The release said that the clinical trials software was a common platform for the collection and management of clinical research data, which would enhance the University's clinical trial capability and provide a platform for running national and international multi-centre trials in complementary medicine.
Evado is a private company

FERMISCAN

Fermiscan says it will acquire the assets of a Perth, Western Australia-based provider of resources sector tradespeople and rename itself to Tempo Australia.
Fermiscan said it would need to change the nature and scale of its activities to comply with ASX Listing Rules and would seek shareholder approval to do so.
Fermiscan failed to commercialize Prof Veronica James’ x-ray diffraction test for breast cancer and acquired then sold the Sydney Breast Clinic and the rights to the intellectual property associated with the test.
Fermiscan raised funds for a number of purposes including development of the diagnostic (BD: Jan 16, Aug 3, 2011) and took legal action against Prof James, with the New South Wales Supreme Court finding in Prof James favor (BD: Jun 5, Nov,11, Dec 16, 2009).
Fermiscan fell 0.3 cents or 13.0 percent to two cents with 49.6 million shares traded.