Biotech Daily

Thursday May 23, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 6%, MEDICAL DEV DOWN 21%**

*** MEDICAL DEVELOPMENTS PROFIT WARNING, MAJOR CSIRO MILESTONE**

*** CONSEGNA OPTION RIGHTS ISSUE RAISES $130k; $252k TO COME**

*** DATAPHARM: 'DAI-SYS TO COMPETE WITH FOREIGN CONTRACTORS'**

*** BIOXYNE, VITALITY DEAL FALLS**

*** COGSTATE TESTS IN MAJOR ALZHEIMER'S STUDY**

*** NUSEP LODGES DENGUE FEVER TEST, TREATMENT PATENTS**

*** IMUGENE LINGUET DELIVERY STARTS WITH VITAMIN D**

*** ANNMAC, CARTHEW, CHAPMAN, NAMPAC SUBSTANTIAL IN AGENIX**

*** BIONICHE CONCERNED INVESTORS QUESTION CORE BUSINESS SALE**

MARKET REPORT

The Australian stock market tumbled 1.99 percent on Thursday May 23, 2013, with the S&P ASX 200 down 103.0 points to 5,062.4 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and four were untraded.

Pharmaxis was the best, up one cent or 5.9 percent to 18 cents, with four million shares traded, followed by Ellex up 5.3 percent to 20 cents with 63,450 shares traded.

Atcor and Tissue Therapies were up four percent or more; Viralytics was up 3.5 percent; both Psivida and Universal Biosensors rose 2.7 percent; Nanosonics was up one percent; with Clinuvel, Mesoblast and Resmed up less than one percent.

Medical Developments led the falls, down 28.5 cents or 21.2 percent to $1.06 with 136,198 shares traded, followed by Phylogica down 16 percent to 2.1 cents and GI Dynamics down 10.45 percent to 60 cents.

Allied Health and Neuren lost more than six percent; Circadian fell 5.8 percent; Patrys, QRX and Reva fell more than four percent; Anteo and Prima were down more than three percent; Alchemia and Cochlear shed more than two percent; Bionomics and Starpharma were down more than one percent; with Acrux, CSL, Heartware and Sirtex down by less than one percent.

MEDICAL DEVELOPMENTS
THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Medical Developments says that although it is making progress on all fronts, net profit after tax for 2012-'13 is expected to be 10 to 15 percent below the previous year.

Last year, Medical Developments said that that total revenue for the 12 months to June 30, 2012 was up 10.9 percent to $11,313,000 with net profit after tax up 55.1 percent to $2,704,024 (BD: Aug 23, 2012).

Today the company said it had invested heavily in its European expansion and operation, US devices business, international regulatory initiatives and research and development and expected to see benefits in 2013-'14.

Medical Developments said it began a research and development program with the Commonwealth Scientific and Industrial Research Organisation last year to create a more efficient, lower manufacturing cost process for the methoxyflurane pharmaceutical compound used in its inhaled Penthrox analgesic device (BD: Jul 5, 2012).

Medical Developments said at that time that the project's catch phrase was "five times the volume at half the cost".

Today Medical Developments chief executive officer John Sharman told Biotech Daily that the CSIRO and his company had "met and exceeded that target at laboratory testing, but not to scale, as yet".

"Methoxyflurane has to be pure to meet regulatory standards," Mr Sharman said. "We have achieved 99.95 percent purity."

"We think we are well on the way, with scale-up to begin in the next two months and we'll know if we are successful in about six months," Mr Sharman said.

"Most of the risk has been dealt with," he said.

"CSIRO came up with the concept of the new 'continuous flow' manufacturing process which they saw in the mining industry and is not yet used in the pharmaceutical industry," Mr Sharman said.

Mr Sharman said that it its European marketing application for Penthrox was expected to be lodged with the UK Medicines and Healthcare products Regulatory Agency (MHRA) in August 2103, following a further cardiac safety study, with approval hoped for within 12 months.

Medical Developments said that its Space Chamber Plus and Space Chamber Compact Asthma devices had been approved by the MHRA for reimbursement in the UK from April 1, 2013 and the company had engaged a contract sales force of 40 people who were selling the products, with first orders received.

Mr Sharman told Biotech Daily that the application to sell Space Chambers in the US was proceeding and the company hoped to have approval in august 2013 with sales beginning in the US in January 2014.

Medical Developments fell 28.5 cents or 21.2 percent to $1.06.

CONSEGNA GROUP

Consegna says its options rights issue has raised $129,735 through applications for 32,433,765 options at 0.4 cents an option.

Consegna said the shortfall was 62,966,235 options and it had notified the underwriter Peloton Capital and expected to raise a further $251,865 (BD: Apr 18, 2013).

Consegna fell 0.1 cents or four percent to 2.4 cents.

DATAPHARM

Datapharm says it has formed a consortium of contract research organizations and service providers called Dai-Sys to drive down costs and compete with foreign companies.
Datapharm said that global contract research organizations were “no longer the obvious choice for companies looking to run international clinical trials” and there was a push to locally based contract research organizations (CROs) that were connected internationally to drive down research and development costs and leverage local know-how and quality.
Datapharm chief executive officer Dr Helen Allars said that Dai-Sys was “a unique international industry co-operative to provide support to bio-product developers”.
“Dai-Sys offers an innovative non-bureaucratic system that is cost competitive with lower overheads using local rates and high quality experienced local organizations- members are selected for their knowledge of local issues with a history of success,” Dr Allars said.
Dr Allars said that Dai-Sys CRO Plus had representation in more than 18 countries, with coverage in Europe, Latin America, Australia and New Zealand.
Dr Allars said that the group included Datapharm, Altiora, MTZ Clinical Research, Latam Clinical Trials, Larix and Syncro.
“Datapharm has many CRO friends globally and we are currently in discussions with a number of companies regarding extending the Dai-Sys membership in Asia, Africa and North America,” Dr Allars said.
“We also want to hear from other CROs, who may be interested in being involved,” Dr Allars said.
Datapharm said that the Dai-Sys model was an alternative to multinational organizations, linking medium-sized to small experienced contract research organizations together into a homogenous team for international clinical trials.
“It is based on principals of transparency between all parties and guaranteed quality of service providers through selection criteria and auditing,” Dr Allars said.
She said that with Datapharm’s technology partner Merge Healthcare can provide electronic data capture in 14 languages and the system is adaptable for provision of any language.
Dai-Sys can be contacted through Datapharm in Sydney.

BIOXYNE

Bioxyne says the proposed acquisition of Vitality Pty Ltd has been terminated.
In February, Bioxyne said it had a non-binding agreement to acquire Vitality, with Bioxyne’s major shareholder Phillip Asset Management proposing to invest up to $2.5 million (BD: Feb 18, 2103).
Bioxyne said at that time that Vitality was established in January 2012 by former Chemgenex executives Dr Greg Collier and Dr James Campbell as a sales and distribution business, focusing on high value medical devices was focused on chronic heart failure and diabetes markets in Australia and Asia and had distribution agreements for the Optimizer III and Diamond devices (BD: Feb 20, 2012).
Today, Bioxyne said that despite regulatory approvals, market uncertainties together with issues relating to the distribution agreements, which arose during the due diligence process, resulted in a higher risk profile for the transaction compared to the initial findings.
Bioxyne said it had undertaken negotiations with Vitality and the licensors to resolve the issues and was unable to reach a satisfactory outcome.
Bioxyne chairman Tony Ho said the company was “disappointed that an alternative solution could not be reached with Vitality and its licensors”.
Bioxyne was untraded at 1.3 cents.

COGSTATE

Cogstate says it has been selected as part of the battery of cognition tests in a study investigating the early detection of Alzheimer's disease.

Cogstate said that the 120-patient, phase II/III study was being run by international research partnership Dominantly Inherited Alzheimer Network (DIAN) at Washington University School of Medicine in St Louis and would evaluate whether two investigational drugs, Roche's Gantenerumab and Lilly's Solanezumab, being developed for Alzheimer's disease, could halt or reverse pathological changes in the preclinical biomarkers known to be present in patients with the disease.

Cogstate said its tests were the only computerized cognitive tests included in the study.

The company said that of the 210 patients, 120 carried a gene mutation linked to a rare form of Alzheimer's disease, but had not demonstrated symptoms of the disease.

Cogstate said that the remaining trial participants did not carry the gene, but had a parent with the gene mutation.

The company said that the study was being run at 30 investigational sites in the US, UK, Canada, Australia and Europe.

Cogstate chief executive officer Brad O'Connor said the trial was "one of the most important global studies in the early treatment of Alzheimer's disease".

Washington University neurology professor and trial director Prof Randy Bateman said that cognitive testing was an important part of the trial and the tests "may provide valuable insights into the earliest mental changes in pre-symptomatic Alzheimer's disease".

"We are excited to move forward with this trial to determine whether it is possible to prevent or slow the onset of Alzheimer's in patients who are genetically destined to develop the disease," Prof Bateman said.

Cogstate said that participants would undergo positron emission tomography brain scans to track amyloid levels in the brain and would have their memory function and other cognitive abilities tested with its computer-based tests.

Cogstate was up three cents or 9.1 percent to 36 cents.

NUSEP

Nusep says it has lodged Australian patent applications to develop a diagnostic and a therapeutic for Dengue haemorrhagic fever based on its Prime technology.

Nusep said that it had shown the ability of the Prime technology to isolate and purify blood cells such as platelets, which were crucial in the treatment of severe dengue.

The company said that the ability to separate cellular material would have applications in other areas, not least of which was blood-borne toxin removal.

Nusep said it had lodged four patent applications covering the use of the Prime technology to provide an effective blood test for the early diagnosis of Dengue fever; produce a hyperimmune plasma for the treatment of Dengue fever from recovered patients; and provide a dialysis treatment based on removal of viral particles and toxins.

The company said that an estimated 500,000 people with severe Dengue fever required hospitalization each year, including a large proportion of children and about 2.5 percent of patients would die.

Nusep said there was no specific treatment but early detection and access to proper medical care lowered the fatality rate below one percent.

The company said that existing tests could only detect Dengue once the disease was in its acute phase and there were no vaccine or therapeutic treatment for Dengue fever and its Prime technology could offer a faster, more accurate and effective alternative.

Nusep fell 0.1 cents or 1.9 percent to 5.2 cents.

IMUGENE

Imugene says laboratory testing of its Linguet vitamin D to monitor the transport across the mouth's buccal mucosa is due for completion by October, 2013.
Imugene said it had completing feasibility testing and formulation development and once the pharmaco-kinetic studies were completed it would begin a bioequivalence clinical study to assess the relationship between two preparations of Linguet vitamin D in the same dosage form.
The company said it expected to file for regulatory approval in the UK by July 2014.
Imugene said the Linguet technology enabled the active ingredient of drugs to be absorbed straight into the bloodstream when placed inside the cheek via the buccal mucosa or under the tongue.
The company said that the tablet form could improve the efficacy and safety of a range of prescription and over the counter medicines.
Imugene chief executive officer Dr Nick Ede said that vitamin D was the initial project with other active ingredients being evaluated.
Imugene said that global sales of vitamin D supplements were growing but there were "serious limitations with the existing treatments".
The company said that oral vitamin D supplements were absorbed through the gastro-intestinal tract erratically and led to transient surges of Vitamin D in the blood stream, limiting the effectiveness of the treatment and in some cases resulting in toxicity.
Imugene said that it had filed a further provisional patent for Linguet protected the formulations designed to deliver both colecalciferol (vitamin D3) and 25-hydroxy vitamin D (calcidiol) more efficiently into the bloodstream.
Imugene said that "several pivotal studies published by Australian medical and academic institutions in 2012 point to the seriousness of Vitamin D deficiency in the Australian population".
Deakin University chair of exercise and ageing Prof Robin Daly said that vitamin D deficiency was "a major health problem worldwide".
"It is clear from the results of our study that, despite an abundance of vitamin D rich sunlight, Australians are not immune from this issue," Prof Daly said.
"Low levels of vitamin D can contribute to a number of serious, potentially life-threatening, conditions such as softened bones; diseases that cause progressive muscle weakness leading to an increased risk of falls, osteoporosis, cardiovascular disease, certain types of cancer and type 2 diabetes," Prof Daly said.
Imugene said that a study led by Prof Daly published in Clinical Endocrinology showed that "31 percent of the population was vitamin D deficient and nearly three quarters had levels considered by many experts as below the optimal for musculoskeletal health".
Imugene was untraded at 0.6 cents.

AGENIX

Annmac Investments as trustee for the Anne McNamara Investment Trust increased its share-holding in Agenix but has been diluted through a rights issue at three cents a share.
In the change of substantial shareholder notice, Annmac said it increased and was diluted from 6,010,073 shares (15.21%) to 9,540,785 shares (10.86%).
Lindsay Murray Carthew as Trustee for the Lindsay Carthew Family Trust said he became substantial with 8,007,968 shares or 9.12 percent of the company.
Craig Graeme Chapman ATF Nampac Discretionary Account became substantial with 12,606,614 shares or 14.35 percent of the company.
Agenix was up 0.1 cents or 3.45 percent to three cents.

BIONICHE LIFE SCIENCES

Bioniche shareholders who have called for a spill of the board have questioned the proposed sale of its animal health assets (BD: May 14, 2013).

A leader of the investor group, William Wells, said in a media release that the animal health business was “the jewel in Bioniche's crown” (BD: Apr 24, 29, 2013).

“It is the only business in the company that produces revenues and positive cash flows and is highly scalable,” Mr Wells said.

“The remaining development programs, centered around Econiche and Urocidin, produce no revenues, burn cash and have to date destroyed shareholder value with no payoff visible for years, if ever,” Mr Wells said.

“Now Bioniche's management and board have decided to divest the animal health business, the core of the company, leaving shareholders with an interest in two non-revenue producing products with a troubled development history and large, idle manufacturing facilities,” Mr Wells said.

Mr Wells said that the sale of animal health announcement did not address the use of proceeds from the divestiture of the animal health business.

Mr Wells said that previously Bioniche sold its sterile injectibles manufacturing subsidiary to a private equity firm, which in turn re-sold it for significantly more than it paid for it.

He said that as concerned shareholders “we have a plan to revive the company [but] Canadian proxy rules restrict us from discussing our plan with shareholders until the Bioniche board calls the special shareholders' meeting in response to our requisition”.

Mr Wells said that the Bioniche board was obstructing the meeting and should immediately call the special shareholders' meeting to ensure a proper dialogue and to allow shareholders to be heard”.

Bioniche was untraded at 35 cents.