Biotech Daily

Thursday October 29, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ALCHEMIA UP 7%; TISSUE THERAPIES DOWN 12%**

*** VICTORIA: $3m FOR BREAST RECONSTRUCTION; $750k FOR HEALTHLINX**

*** PHARMAXIS FILES BRONCHITOL CYSTIC FIBROSIS EU APPLICATION**

*** BIOTA'S $24.1m SEPTEMBER QUARTER RELENZA ROYALTY**

*** MEDICAL THERAPIES LICENCES LUNG MIDKINE TO CELERA; CASH BURN**

*** ROYAL ADELAIDE JOINS VIRALYTICS' HEAD, NECK CANCER TRIAL**

*** CIRCADIAN LEGAL FIGHT WITH ARK OVER VEGENICS VEGF-D LICENCE**

*** COMPUMEDICS 4th GERMAN SALE; $1.3m IN 6 MONTHS**

*** DAVID ROSA REPLACES SUNSHINE HEART CEO DON ROHRBAUGH**

*** CHEMGENEX VOTES ON 2.2m OPTIONS FOR CEO DR GREG COLLIER**

*** STARPHARMA WITHDRAWS 1.9m CEO SHARES, CITES TAX LIABILITY**

*** JM FINANCIAL CLIENTS TAKE 5% OF GENERA**

MARKET REPORT

The Australian stock market fell a further 2.4 percent on Thursday October 29, 2009 with the S&P ASX 200 down 110.4 points to 4574.7 points. Four of the Biotech Daily Top 40 stocks were up, 28 fell, seven traded unchanged and one was untraded.

Alchemia was best, up four cents or 6.6 percent to 65 cents with 266,235 shares traded, followed by Uscom up 5.7 percent to 74 cents, Novogen up 2.54 percent, CSL up 1.4 cents and Peplin up 0.57 percent.

Tissue Therapies led the falls, down two cents or 12.1 percent to 14.5 cents with 1.0 million shares traded. Phylogica, Benitec and Sunshine Heart lost 10 percent or more; Living Cell fell 9.1 percent; Antisense was down 8.6 percent; Bionomics, Biota, Nanosonics and Sirtex were down more than five percent; Cathrx fell 4.8 percent; Chemgenex, Clinuvel, Labtech, Universal Biosensors and Viralytics were down more than three percent; Avexa, Circadian, Compumedics, Heartware, Phosphagenics and Prana shed more than two percent; with Acrux, Cellestis, Genera and Pharmaxis down more than one percent.

VICTORIA GOVERNMENT, ATEC, HEALTHLINX

The Victoria Government will provide $2.95 million for a researcher collaboration to find an alternative to silicon in breast reconstruction after mastectomy.

A grant of $750,000 was awarded to Healthlinx to further develop its Ovplex ovarian cancer test.

Innovation Minister Gavin Jennings said the breast reconstruction project was important in the treatment and recovery of women with breast cancer.

The Australian Tissue Engineering Centre will lead the breast reconstruction project in partnership with Anatomics, Cogentum, the Bernard O'Brien Institute of Microsurgery, Melbourne's St Vincent's Hospital, the University of Melbourne's Department of Chemical and Biomolecular Engineering and the Victorian Institute of Forensic Medicine.

Innovation Minister Gavin Jennings said the Government funding research to find a procedure to reconstruct breasts after mastectomy that avoids using silicon.

"The technique involves the insertion of a customized biodegradable chamber which is contoured to match the woman's natural breast shape within which the permanent fat found in breasts can be grown," Mr Jennings said.

"Where there is insufficient fat, the researchers intend to develop Myogel, a muscle derived tissue that induces fat tissue production. This technique provides a safe and more natural way of reconstructing the breast," Mr Jennings said.

Mr Jennings said that breast cancer survivors can experience a range of difficulties, ranging from physical limitations to psychosocial problems.

He said self esteem derived from feeling better about their bodies through breast reconstruction was an important factor in their recovery.

"Breast cancer is the most common cancer among women in Australia," Mr Jennings said. "More than 13,600 new cases are expected this year while around 106 Australian men are also expected to be diagnosed," he said.

A Victoria Government media release said the project was one of 10 health projects funded under the $41 million Victoria's Science Agenda Investment Fund.

The Government said other projects to be funded under the VSA Investment Fund included an Australian Collaborative Care Cluster for chronic disease; collaboration to develop next generation pharmaceutical formulations; high-value clinical products for oncology diagnosis and therapy; electronic tracking for storage of cord blood and stem cells; capturing the therapeutic value of dairy bioactives; and nanosecond laser treatment for vision loss from age-related macular degeneration.

PHARMAXIS

Pharmaxis says it has filed an application with the European Medicines Agency (EMEA) to market Bronchitol in Europe for cystic fibrosis.

Pharmaxis chief executive officer Dr Alan Robertson said it was an "important milestone in bringing Bronchitol to the worldwide cystic fibrosis community".

"Since reporting positive results from our first phase III trial in May of this year, a dedicated team within Pharmaxis has compiled the comprehensive electronic submission required and I am pleased to say it has been filed overnight with the EMEA," Dr Robertson said.

"Our marketing authorization application is being reviewed through the European Union's centralized procedure and will, if successful, give us immediate access to all European Union member countries," Dr Robertson said.

He said the applications review was expected by the end of 2010 and there were about 40,000 people in Europe with cystic fibrosis.

Pharmaxis fell five cents or 1.9 percent to $2.54.

BIOTA

Biota expects to receive a royalty payment of $24.1 million from Glaxosmithkline for $3315 million sales of Relenza in the three months to September 30, 2009.
The royalty payment follows the previous quarter indicative royalty of $8.9 million and $32.3 million for the three months to March 31, 2009.
Biota fell 17 cents or 5.7 percent to $2.81.

MEDICAL THERAPIES

Medical Therapies said it has licenced the use of its midkine patent portfolio for the development of novel lung cancer diagnostics to the California-based Celera Corp.
Medical Therapies chief executive officer Maria Halasz told Biotech Daily that the terms of the agreement's up front fees and milestone payments were confidential but would be "significant once royalties come-in, in three to four years".
The company said Celera would be able to use its midkine patents for the development and commercialization of diagnostic products to address a range of lung cancer-related applications, including risk assessment, early detection, differentiation, prognosis as well as monitoring of reoccurrence and disease progression and response to treatment.
Medical Therapies said blood midkine levels were greatly elevated in the early stages of cancer formation and poor prognosis for patients had been closely linked to high midkine levels in a number of cancers.
Celera's vice-president of proteomics Dr Steve Ruben said his company had used "a novel mass spectrometry-based approach to identify potential circulating protein biomarkers for non-small cell lung cancer".
"We believe that midkine could have an important role in a blood-based immunodiagnostic assay and are pleased to be able to incorporate midkine in our on-going research and validation activities towards the development of a method to detect lung cancer using a simple blood test," Dr Ruben said.
Separately Medical Therapies said its net operating cash burn for the three months to September 30, 2009 was $422,000 with cash at the end of the quarter of $264,000.
Medical Therapies said expenditure was unusually high due to costs of assignment of its patent portfolio and "redundancy costs pursuant termination of an employee".
The company said it was in the process of appointing a broking firm to assist with a capital raising and income was expected from the Celera agreement.
Medical Therapies was up 0.5 cents or 16.7 percent to 3.5 cents with 53.6 million shares traded.

VIRALYTICS

Viralytics has added the Royal Adelaide Hospital as a third centre for its phase I Cavatak head and neck cancer trial.
Royal Adelaide Hospital oncologist Dr Anne Taylor said the hospital was looking forward to the collaboration and hoped it would play a part in unveiling virotherapy, the use of common viruses to attack a range of cancers, as an accepted treatment for late stage head and neck cancers.
Viralytics' managing director, Mr Bryan Dulhunty, said trials into the use of virotherapy were gaining momentum, with two companies undertaking phase III studies of their respective oncolytic viruses.
Viralytics fell 0.1 cents or 3.45 percent to 2.8 cents with 1.5 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian subsidiary Vegenics has terminated the VEGF-D licence to Ark Therapeutics for use in Ark's Trinam product, for non-payment of fees.

Circadian said Trinam was in phase III clinical trials to extend the functioning of intravenous access grafts used by kidney dialysis patients.

Circadian said that through Vegenics it would commence arbitration proceedings against Ark's Finnish subsidiary Lymphatix Oy to rule out Ark's claim that it retains a licence covering the use of Vegenics' intellectual property in Trinam through Lymphatix. The company said Lymphatix had a licence from Vegenics for certain vascular endothelial growth factor (VEGF) C and D gene therapy rights.

Circadian said Lymphatix and its parent Ark had no rights to use Vegenics' intellectual property to sell Trinam under the Lymphatix license.

Circadian said it had initiated the actions "to ensure that these matters can be resolved and clarified before Trinam comes to the market in the next two to three years, assuming ongoing phase III trials are successful".

Circadian said arbitration might take up to 12 months and the associated time and costs were not expected to have a significant effect on management resources or overall operating expenditures.

Circadian chief executive officer Robert Klupacs said it was "disappointing that it has been necessary to take this action to enforce our rights, despite our attempts to rectify the disputes with Ark and Lymphatix".

"We are confident in our position that neither Ark nor Lymphatix have rights to market Trinam using our VEGF-D technology through the Lymphatix licence which we expect to resolve through the arbitration process," Mr Klupacs said.

Circadian said that in 2001 the Ludwig Institute for Cancer Research and the University of Helsinki commercial arm Licentia granted Ark a non-exclusive licence under its VEGF-D intellectual property to exploit the VEGF-D gene therapy combination product, now branded as Trinam by Ark, in return for an upfront fee, minimum annual royalties, product development milestone payments and royalties on sales.

Ark is developing Trinam to inhibit the closure of vascular grafts in renal dialysis patients.

In 2004 Ludwig, Licentia and founding scientists formed the Finnish company Lymphatix Oy.

Ludwig and Licentia granted that company an exclusive licence to develop VEGF-C and VEGF-D gene therapy products.

It is Circadian's position that the Lymphatix licence expressly excludes rights previously granted to a third party.

In 2007 Ludwig and Licentia assigned all of their interest in VEGF-C and VEGF-D to Vegenics and the Ark licence and the Lymphatix licence were novated to Vegenics with Vegenics taking over all rights and responsibilities as licensor.

In 2008 Lymphatix was acquired by Ark.

In 2009 Vegenics issued Ark with its annual invoice for payment of the minimum royalty in accordance with the Ark licence.

Ark, which had paid all previous years' fees, refused to pay the 2009 fee.

Circadian said Ark considered that it did not require the Ark licence as it owns Lymphatix, which it considered had the rights to market Trinam using Vegenics' VEGF-D intellectual property.

In October 2009 due to Ark failing to remedy its breach of the licence for non-payment; and Vegenics being unable to resolve the dispute over the scope of rights granted to Lymphatix under the Lymphatix License, Vegenics terminated the Ark licence.

Circadian fell 1.5 cents or 2.04 percent to 72 cents.

COMPUMEDICS

Compumedics says the EUR230,000 ($366,000) sleep-diagnostics contract with Berlin's Zentral Sleep Lab Service takes its total German sales to $1.3 million in six months.
Compumedics said Zentral Sleep Lab was "a major sleep diagnostic facility" serving as a referral centre for Germany capital and its surrounding districts, with a population of more than 3.5 million people.
Compumedics said the sales came from its direct-sell model to Gerlingen ($400,000), Offenburg ($300,000), Köln ($353,000) and Berlin.
The company said that "more importantly, the winning of these sales has displaced equipment from a number of incumbent competitors".
"This achievement not only validates Compumedics' direct-sell model in Germany, but also supports the technical superiority and usability of Compumedics' range of sleep diagnostic devices," Compumedics said.
Separately, Compumedics said resolutions to its annual general meeting were passed on a show of hands. The most controversial resolution was the approval of a 20 percent interest convertible note to a company controlled by chairman and chief executive officer David Burton which was passed with 94.6 percent of proxy votes in favor and 5.4 percent of proxy votes against.
Compumedics fell half a cent or 2.8 percent to 17.5 cents.

SUNSHINE HEART

Sunshine Heart says its chief executive officer for the past seven years Don Rohrbaugh, has retired and will be replaced by David Rosa.
Chairman Nicholas Callinan thanked Mr Rohrbaugh for his contribution as chief executive officer and said he had taken the C-Pulse heart cuff from early stage laboratory testing to clinical-readiness and had been pilot tested in Australia and New Zealand and was approved by the US Food and Drug Administration for clinical trials.
Mr Rosa has been appointed chief executive officer from November 1, 2009.
The company said Mr Rosa was based in Minnesota and had 19 years of medical device experience in both large corporations and in start-up companies.
Most recently, Mr Rosa was president and chief executive officer of a Minneapolis-based start-up company. He was previously vice-president of world-wide marketing of cardiac surgery and cardiology for St Jude Medical and had product management and sales experience with Sci-Med, a division of Boston Scientific as well as Stryker Medical.
Mr Rosa has a Bachelor of Science from Drexel University and an MBA from Duquesne University.
Sunshine Heart's annual general meeting reelected directors Dr Geoff Brooke and John Brenna with 330 million proxy votes in favor and 20,397,163 proxy votes against.
Sunshine Heart fell half a cent or 10 percent to 4.5 cents.

CHEMGENEX

Chemgenex shareholders will vote on the issue of up to 2,180,000 options exercisable at 43 cents to chief executive officer Dr Greg Collier.
The annual general meeting will also consider the re-election of directors Dr Geoff Brooke and Daniel Janney as well as the ratification of a prior share issue.
The meeting will be held at RBS Morgans, Level 27, 367 Collins Street Melbourne on November 30, 2009 at 11am.
Chemgenex fell three cents or 3.85 percent to 75 cents.

STARPHARMA

Starpharma has withdrawn an annual general meeting resolution granting 1.9 million "appreciation shares" to chief executive officer Dr Jackie Fairley (BD: Oct 12, 2009).

Starpharma said employee share scheme legislation introduced into Federal Parliament on October 21, 2009, would have unfavorable tax implications for Dr Fairley.

The company said in the notice of meeting that the grant of share appreciation rights may be subject to favorable private tax rulings being obtained from the Australian Taxation Office.

Under previous ATO rulings, these types of rights were never "rights to acquire shares" and, accordingly, an employee would only be subject to the employee share scheme rules if, and when, the rights were satisfied by issuing shares.

Starpharma said the ATO subsequently issued a private tax ruling confirming this position under existing legislation.

Starpharma said the recently released legislation contained unexpected measures that were not included in the exposure draft of the legislation or earlier consultation papers issued by the Government and which, if adopted, would negate the private ruling.

Starpharma said the Government had "elected to expand the application of the employee share scheme provisions to share appreciation rights, with potentially serious adverse tax consequences for current and future holders of those rights".

The company said it had achieved superior performance under the stewardship of Dr Fairley and has achieved a number of significant milestones during this period.

The board will take further advice before proposing an alternative long term incentive plan to provide appropriate reward and incentive for Dr Fairley.

A spokesman for the Assistant Treasurer Senator Nick Sherry told Biotech Daily that "concerns were raised that certain schemes involving the possible provision of either [employee share scheme] interests or cash, were not being effectively taxed".

"It is understood that these 'indeterminate rights' are primarily provided to high level executives," the spokesman said in a written email response.

"The purpose of characterizing these rights as 'indeterminate rights' is often to exploit the tax laws to maximize the periods of deferral and minimize any tax paid," he said.

"If there's one thing that everyone agrees on, it's that these schemes have been exploited particularly by people on very high incomes. The changes protect the tax base and cut down on potential avoidance and confusion by those using employee share schemes at the high end," the spokesman said.

Starpharma fell half a cent or 0.9 percent to 57 cents.

GENERA BIOSYSTEMS

JM Financial Group has become a substantial shareholder in Genera with a holding of 2,625,280 shares or 5.0 percent.

The Melbourne-based JM Financial Group said it managed the shares "held in client discretionary investment accounts" with Sandhurst Trustees the registered holder.

The most recent acquisitions were 158,325 shares for $104,280.99 or 65.9 cents a share.

Genera fell 1.5 cents or 1.7 percent to 85 cents.