Biotech Daily

Wednesday May 26, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CATHRX UP 16%; STARPHARMA DOWN 7%**

*** AVEXA EGM TO ROLL CHAIRMAN NATHAN DRONA, ELECT DIRECTORS**

*** FDA PETITION TO SUPPORT CHEMGENEX'S OMAPRO FOR CML**

*** US JUDGE PROVIDES REGIONAL COVER FOR ATCOR'S SPHYGMACOR**

*** IMMURON COW COLOSTRUM PRODUCT NEUTRALIZES HIV IN VITRO**

*** NUSEP RIGHTS ISSUE RAISES $4.5m**

*** SUNSHINE HEART INVESTOR BRIEFING TOUR**

MARKET REPORT

The Australian stock market climbed 0.98 percent on Wednesday May 26, 2010 with the S&P ASX 200 up 41.9 points to 4307.2 points.

Ten of the Biotech Daily Top 40 stocks were up, 10 fell, 11 traded unchanged and nine were untraded.

Cathrx was best, up 2.5 cents or 16.1 percent to 18 cents with 46,145 shares traded, followed by Avexa up 13.3 percent to 3.4 cents with 22.0 million shares traded.

Sunshine Heart climbed 6.1 percent; Bionomics was up five percent; Acrux was up 4.7 percent; Pharmaxis and Viralytics rose more than two percent; with Chemgenex, Impedimed and Nanosonics up more than one percent.

Starpharma led the falls, down four cents or 7.4 percent to 50 cents with 62,524 shares traded, followed by Universal Biosensors down eight cents or 5.8 percent to $1.30 with 440,000 shares traded.

Phosphagenics lost 3.1 percent; Novogen and Tissue Therapies shed more than two percent; with Clinuvel, CSL and Sirtex down more than one percent.

AVEXA

Avexa shareholders will vote on a resolution to replace chairman Nathan Drona and recently appointed director Uri Ratner with Bruce Hewett and Stephen Crowley.

Avexa was left with $23 million in cash following the closure of its apricitabine or ATC program for HIV (BD: May 10, 2010).

The company said at that time that it closed the program after failing find a licencing partner (BD: May 20, 2010).

On May 20, 2010, Avexa announced the resignation of director Joe Baini, to be replaced by Uri Ratner, formerly of Passport Capital, which Avexa said at that time was once the company's largest shareholder. Due to an absence of substantial and ceasing shareholder notices as Passport Capital reduced its holding, Biotech Daily and the ASX have not been able to verify this claim.

Avexa said the resolutions were called by shareholders with representing about 5.3 percent of the company, but did not identify the signatories.

Biotech Daily has requested the release of the requisition document to discover who has called the meeting but Avexa has not been able to comply.

"The requisitioning shareholders have been invited but have elected not to disclose their intentions or agenda," Avexa said.

The record date for attending the meeting and voting on the resolutions is 7pm on Sunday July 4, 2010.

Avexa said its board recommended shareholders vote against the four resolutions which call for the removal of Mr Drona as chairman and a director; the appointment of Mr Crowley and Mr Hewett as directors; and the removal of any director appointed between May 6, 2010 and the date of the meaning, which includes Mr Ratner who was appointed on May 19, 2010.

Avexa made a number of claims regarding the meeting including the possibility that the new directors might commit more funds to the ATC program which Avexa said "would be an extremely poor use of shareholders funds with a very low chance of a successful outcome".

Should the resolutions succeed the new board would compose continuing director David Bottomley, Mr Hewett and Mr Crowley.

Avexa said if all resolutions are passed, "control of the board … would lie with individuals who have not disclosed to shareholders their relevant skills, intentions or strategy for the company".

Biotech Daily has established that Mr Hewett is the principal consultant of Rx Connect whose website says he is a registered pharmacist.

The website says Mr Hewett joined Johnson & Johnson subsidiary Janssen-Cilag in Sydney as a product specialist in biotechnology and was Faulding Pharmaceuticals general manager for Australia and New Zealand.

It says that in 2006 Mr Hewett founded Max Pharma which was acquired in 2009.

Biotech Daily has spoken briefly with Mr Hewett who is on leave returning to Melbourne in early June.

Mr Crowley has text messaged Biotech Daily to say he is away from his usual place of work and will make contact next week.

Mr Crowley is believed to have worked with Janssen-Cilag and is a part-time senior lecturer at the University of Melbourne's Centre for Health Policy, Programs and Economics.

The meeting will be held at Computershare Conference Centre, 452 Johnston Street, Abbotsford, Victoria on July 6, 2010 at 10am.

Avexa was up 0.4 cents or 13.3 percent to 3.4 cents with 22.0 million shares traded.

CHEMGENEX

Chemgenex's omacetaxine mepesuccinate for chronic myeloid leukemia is believed to be the first Australian drug supported by a petition to the US Food and Drug Administration.

The North American petition calls for "clarification on the standing of the drug omacetaxine mepesuccinate and the issue of non-standardized in-vitro diagnostics".

Responsibility for the petition to the US Food and Drug Administration's Oncologic Drugs Advisory Committee has been taken by the US National CML Society and the CML Society of Canada and was written by Cheryl-Anne Simoneau and Greg Stephens.

The petition had 142 signatories at the time of publication and is believed to be the first petition to the FDA supporting an Australian developed drug, although petitions for drugs in development is not unknown.

Chemgenex had a meeting with the Oncologic Drugs Advisory Committee regarding omacetaxine mepesuccinate but instead of a question on approval the Committee was asked whether the drug required a diagnostic test (BD: Mar 23, 2010).

A majority of the committee agreed the test was required, but two leukemia specialists on the Committee said if the question was for approval they would have voted 'yes'.

"We, CML (chronic myelogenous leukemia) patients, our families, and physicians, formally petition the FDA to clarify its decision regarding the questioning of the specific mutation testing to detect the T315I mutation in the subset of TKI resistant CML patients," the petition said.

It said tests to monitor CML patients during treatment were: bone marrow karyotype; fluorescent in situ hybridization; and polymerase chain reaction testing.

"It is our understanding that these tests/assays are not currently standardized, nor are they approved by the FDA.

"However, they are validated tools in use for decades, well defined and understood in the scientific, medical and patient community.

"Clinicians who specialize in the treatment of CML rely on the results of these tests, directly and entirely, to guide treatment decisions.

"Indeed, every single form of drug therapy for CML, currently available commercially and approved by the FDA, was brought to market utilizing information based on the efficacy data relying on the performance of these specific non standardized, non FDA approved tests," the petition said..

"Omacetaxine Mepesuccinate appears to be a clear potential treatment option for CML patients harboring the T315I mutation, as well as for those with failure of other approved therapies for CML, namely the kinase inhibitors Imatinib, Dasatinib, and Nilotinib. One might consider these patients as orphans within an orphan disease, and treatment options, aside from stem cell transplant, are currently nil," the petition said.

The petition said that based on the points above, clarity was needed in defining standardization requirements for diagnostics in CML.

"Additionally, with the recent decisions, not in cohesion with current diagnostics used and accepted by the FDA, the unmet need of a limited population, the activity of a novel therapeutic drug, and the relegation of the T315I mutation as a marker defining a target population and not a disease response requirement, we would ask that the review of omacetaxine mepesuccinate, in particular the requirement for a standardized T315I mutation assay be reconsidered," the petition said.

"Most importantly, we ask that the FDA allow omacetaxine mepesuccinate to come to market while they collaborate with lab experts on the design of a standardized test," the petition said.

The signatories include CML patients, advocate groups and investors in Chemgenex.

Chemgenex was up half a cent or 1.72 percent to 29.5 cents.

ATCOR MEDICAL

Atcor says the US Office of Medicare Hearings and Appeals has required a major insurer to provide coverage for its Sphygmocor central blood pressure measure.
Atcor said that an administrative law judge found that the Michigan-based Blue Cross Blue Shield which operates a Medicare health plan "must provide coverage for use of the Sphygmocor System".
Atcor said a physician used the Sphygmocor system to treat a high-risk patient with an extensive history of hypertension, whose blood pressure was previously uncontrolled using standard brachial cuff blood pressure for drug therapy selection and guidance.
Atcor said the use of its system enabled the physician to control her blood pressure, improve her cardiac function and reduce target organ damage.
Atcor said that a number of private health plans reimbursed physicians for Sphygmocor assessments using an unlisted cardiovascular services code.
Atcor's chief financial officer Peter Manley told Biotech Daily that the insurer refused to reimburse the doctor who then appealed to the Department of Health and Human Services' Office of Medicare Hearings and Appeals.
Atcor said that the US Medicare was a Federal Government plan for people over 65 years and those with certain disabilities and covered more than 45 million Americans.
Medicare is administered primarily by private contractors on a state or regional basis and Blue Cross Blue Shield covered more than five million people in four states.
Atcor chief executive officer Duncan Ross said the decision was "a significant step forward in the clinical adoption of Sphygmocor in the US market".
Atcor said it would continue "to drive clinical adoption through local reimbursement decisions and the company remains on track to file for a common procedural terminology (CPT) code specific to central blood pressure assessment as early as November 2010.
Atcor was unchanged at 14 cents.

IMMURON

Immuron says a conference poster shows that its antibody product neutralises HIV transmission in vitro and discusses its potential for preventing HIV transmission.
Immuron said the poster entitled 'Potent Low-Cost Neutralising Antibodies against HIV-1 from Hyperimmune Bovine Colostrum' was presented by a researcher at the University of Melbourne's Department of Microbiology and Immunology Dr Marit Kramski at the International HIV Microbicides conference in Pittsburgh, Pennsylvania.
Immuron said Dr Kramski was a member of Dr Damian Purcell's laboratory at the University of Melbourne which was collaborating with Immuron on this project.
The company said the University of Melbourne research team found that the antibodies, generated in cattle and isolated from colostrum, strongly neutralized many isolates of HIV, thus preventing the virus's ability to infect cells.
Immuron said the work led to further funding for proof-of-principle work to investigate if the antibodies made by combining vaccine technologies from the University of Melbourne group and production technologies from Immuron could provide the basis for a safe microbicide method of prevention of HIV transmission.
Immuron's chief executive officer Dr Grant Rawlin said that a "key attraction of this approach to developing a microbicide is that colostrum antibody production is easy to scale-up at a reasonable cost and the product is likely to be suitable for topical use".
"We eagerly await the results of further research which we anticipate will confirm the efficacy of these results and pave the way for human clinical trials," Dr Rawlin said.
Immuron was up 0.2 cents or 3.2 percent to 6.5 cents.

NUSEP

Nusep says its one-for-two rights issue raised $4.5 million with more than $1 million in oversubscriptions above the proposed $3.42 million raising.

Nusep said the funds were to acquire the US-based Bioinquire business and undertake clinical trials to commercialize the Spermsep sperm separation technology.

When it announced the rights issue the company said it hoped to raise $5 million at 20 cents a share (BD: Mar 17, 2010).

Nusep was up one cent or 4.35 percent to 24 cents.

SUNSHINE HEART

Sunshine Heart chief executive officer David Rosa will hold a series of investor briefings in Eastern Australia.

Sunshine Heart said shareholders and interested parties were invited to attend the presentations in Sydney on June 1, 2010 at 10am at RBS Morgans, Sydney Conference Room

Level 7, RBS Tower, Cnr Phillip & Bent Streets, Sydney; in Brisbane on June 2, at 12pm at RBS Morgans, Brisbane Theatre, Level 29, Riverside Centre, 123 Eagle Street, Brisbane; and in Melbourne on June 3, 12pm at RBS Morgans, Melbourne Conference Room, Level 27, 367 Collins Street, Melbourne.

Sunshine Heart implanted the eighth patient in its US trial of its C-Pulse aorta cuff for patients with heart failure (BD: May 24, 2010).

Sunshine Heart was up 0.2 cents or 6.1 percent to 3.5 cents.