

Biotech Daily

Monday November 29, 2010

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market climbed 0.44 percent on Monday November 29, 2010 with the S&P ASX 200 up 20.2 points to 4618.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and six were untraded. All three Big Caps were up.

Alchemia was best, up four cents or 6.45 percent to 66 cents with 136,673 shares traded, followed by Patrys up five percent to 10.5 cents with 386,450 shares traded.

Mesoblast climbed 4.7 percent; Circadian, Cochlear and Pharmaxis rose more than two percent; with Acrux, Bionomics, Chemgenex, Heartware, QRX and Universal Biosensors up more than one percent.

Prana led the falls, down 1.5 cents or 9.7 percent to 14 cents with 474,780 shares traded, followed by Cellmid down 8.5 percent to 4.3 cents with 6.2 million shares traded.

Sirtex lost 7.7 percent; Benitec and Optiscan were down more than six percent; Tissue Therapies was down 5.15 percent; Nanosonics and Prima fell more than four percent; Genetic Technologies, Starpharma and Virax were down more than three percent; with Clinuvel and Viralytics down more than two percent.

BIOTECH DAILY EDITORIAL: SHAREHOLDER VOTING, AGAIN

Every November, Biotech Daily tries to report fairly on the results of annual general meetings and in doing so runs into the problem of non-transparent voting.

Companies must report proxy votes received as well as the "show of hands" in the room, but the numbers of shares attached to those hands is discretionary. Companies do not have to report the number of votes in the room, nor declare in their results the number of shares on issue.

This creates a problem for accurate reporting and in an attempt to be fair to the Prima and Agenix meetings last week, Biotech Daily said it reported "all company meetings where the active vote against a resolution exceeds five percent, the level required to call general meetings."

What should have been made more clear is that five percent of the total share register is required to call a meeting, but in the absence of an accurate count of meeting votes, we report anything above five percent of those who bother to vote, not including abstentions or votes at the discretion of the chair.

In the case of Prima, the increase in non-executive directors' remuneration along with options to directors were opposed by more than 7.4 million proxy votes (11.7%) to more than 53.4 million proxy votes (88.3%) in favor. But in its most recent Appendix 3B statement Prima said it had 743,811,830 shares on issue, reducing the opposition to about one percent of the total shares on issue.

The Agenix resolution on a director and executive equity plan was approved by 4,953,806 proxy votes in favor (62.1%) compared to 3,021,337 proxy votes (37.9%) against, but at its last Appendix 3B Agenix had 718,553,021 shares on issue reducing the opposition to less than half of one percent.

Meanwhile, we are not told how many shares are held in the "show of hands in the room" which for both companies could easily be tens of millions of votes in favor and with no dissent. But we do not know.

One reason for not publishing the total number is the cost of correctly auditing the votes in the room, said to be several thousand dollars. So shareholders and reporters can only guess at what might have happened in the meeting room, because the Corporations Act, the Australian Securities and Investments Commission (ASIC) and the ASX do not require transparent reporting of meeting resolutions. All that is required is that proxy votes be counted.

Where there is a significant number of proxy votes opposing a resolution – and it is most frequent with directors awarding themselves increases in remuneration or stock – Biotech Daily will continue to report the number of 'active' votes.

Until we move to a completely transparent, electronic voting system there is no other way to let investors know the sentiment within the company.

David Langsam Editor

IMPEDIMED

Impedimed says Stanford University's Dr Stanley Rockson has asked the Centers for Medicare and Medicaid Services for reimbursement for an arm lymphoedema registry. Impedimed said the proposed registry for breast cancer patients using bio-impedance spectroscopy would be run by Stanford University's School of Medicine.

Impedimed said it was "the world leader in the development and distribution of medical devices employing bio-impedance spectroscopy technologies for use in the non-invasive clinical assessment and monitoring of fluid status".

The company said its L-Dex bio-impedance spectroscopy was a tool to assist in the assessment of lymphoedema by a medical provider.

Dr Rockson said that "for the first time, I believe that we will derive an accurate assessment of the risk of lymphoedema in breast cancer survivors".

"Not only will we learn valuable lessons about the early natural history of breast cancerassociated lymphoedema, but we will be in a position to document the ability of bioimpedance spectroscopy to accurately diagnose preclinical disease, and thereby, prevent the irreversible complications of this devastating disease," Dr Rockson said.

Impedimed said Dr Rockson was one of two key note speakers to address the November 2009 Medicare Evidence Development and Coverage Advisory Committee Panel called by the Centers for Medicare and Medicaid Services "to address the adequacy of the available evidence that supports the diagnostic and treatment methods used in the management of secondary lymphoedema".

The company said that one of the Panel suggestions, due to the conflicting data associated with conventional methods of detection, was to consider Medicare reimbursement support for the testing costs of a registry using a standardized metric to better understand the natural history of the condition.

Impedimed said the proposed bio-impedance spectroscopy registry and study had the support of the Stanford University institutional review board and the cooperation and collegial support of a US professional society for surgeons.

The company said that should the registry submission be successful, Impedimed would provide funding for the bio-impedance spectroscopy registry through an unrestricted grant. Impedimed said the Centers for Medicare and Medicaid Services would only support reimbursement of testing costs and not the running of the bio-impedance spectroscopy registry.

Impedimed said it would fund the running costs over a three to five year period, to advance the science and clinical validation of bio-impedance spectroscopy under the Federally-sponsored program.

Impedimed chief executive officer Greg Brown said that conventional methods of detecting lymphoedema were "often non-standardized and subjective, resulting in poorly defined incidence rates for the accurate identification of disease".

"Often today the disease is only identified after it has become visibly apparent and at risk of already irreversible changes," Mr Brown said.

"A large US national registry based on the use of a standardized and objective metric, the [Impedimed] L-Dex testing, should facilitate clearer understanding around the true incidence rate and will further validate the benefits of early detection and treatment," Mr Brown said.

Impedimed said that one of the purposes of the Coverage with Evidence Development program was to generate data on the use and impact of a device or service evaluated under a National Coverage Determination so that Medicare could generate clinical evidence for providers' recommendations to Medicare beneficiaries.

Impedimed was unchanged at 84 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has positive results in a clinical study of second point-of-care technology, the PT/INR strip and meter system for blood clotting.

Universal Biosensors said the prothrombin time (PT) assay measured the clotting tendency of blood and was reported as an international normalised ratio (INR).

The company said the system prototype "showed excellent correlation with the current market leader in the \$US400 million point-of-care PT/INR market which bodes well for the next phase of its development, clinical testing and ultimately commercialization".

Universal Biosensors said its system performed a prothrombin time assay on a fingerprick blood sample and reported the results as an INR to support immediate therapy management.

The company said the PT/INR would be the first product after its Johnson & Johnson Lifescan Onetouch Verio diabetes test (BD: Jan 28, 2010).

Universal Biosensors said the system used its electrochemical technology and targeted the second largest point-of-care market segment after blood glucose.

Universal Biosensors said a clinical study compared its prototype PT/INR system with the Roche Coaguchek XS and was conducted at a site in the US and at Universal Biosensors' facility in Melbourne with 53 subjects taking warfarin and 16 subjects not taking warfarin. The company said the study showed a strong correlation between the performance of the two systems, as well as the reproducibility of results using the prototype.

Universal Biosensors said the results provided confidence that the prototype system was capable of competing with existing products based on the industry standard.

The company said the point-of-care PT/INR testing market was valued at more than \$400 million worldwide and was expected to increase to more than \$1 billion by 2020.

Universal Biosensors said point-of-care PT/INR testing was used to evaluate patients taking the anti-coagulant warfarin, enabling immediate dose adjustments.

The company said that in the US about 30 million warfarin prescriptions were filled each year and patient self-testing had become the fastest growing segment within the PT/INR market.

Universal Biosensors said market growth had been driven by changes to the US Medicare reimbursement schedule with coverage for home INR monitoring expanded to warfarin patients with atrial fibrillation and venous thrombo-embolism.

Universal Biosensors was up two cents or 1.3 percent to \$1.55.

NUSEP

Nusep says it has raised \$1.9 million through the placement of 8,972,513 shares at 21 cents a share.

Nusep said the placement by Stonebridge Securities was for its \$S4 million (\$A3.1 million) investment in Singapharm Pte Ltd (BD: Nov 25, 2010).

Nusep was up two cents or 7.1 percent to 30 cents.

<u>ACRUX</u>

Orbis Investment Management has reduced its substantial holding in Acrux from 27,078,251 shares (16.59%) to 25,395,773 shares (15.56%).

The substantial shareholder notice said Orbis sold the 1,682,478 shares between November 3 and November 25, 2010 for \$5,312,845 or an average price of \$3.16 a share. Acrux climbed six cents or 1.8 percent to \$3.33.

MESOBLAST

All resolutions to Mesoblast's annual general meeting were passed, with up to 23.0 percent of votes cast opposing the remuneration report and the employee option plans. The greatest dissent was over the employee option plan "to facilitate the issue of incentive stock options to residents of the United States of America", in which a total of 12,101,249 proxy votes (23.0%) opposed the plan with 40,464,689 proxy votes (67.0%) in favor. The remuneration report and the employee share plans faced similar opposition, but the constitutional amendment was passed overwhelmingly.

Mesoblast's most recent Appendix 3B share issue announcement said there were 158,140,556 shares on issue, meaning that opposition to the resolutions came from 7.65 percent of all shares on issue.

. Separately, Mesoblast said that director Byron McAllister had resigned. Mesoblast was up 15 cents or 4.7 percent to \$3.34.

<u>CHEMGENEX</u>

All resolutions to the Chemgenex annual general meeting were passed, with up to 5.6 percent of votes cast opposing the remuneration report and the employee option plans. The greatest dissent was against the remuneration report with 9,696,259 proxy votes (5.6%) opposed and 163,215,821 proxy votes (94.4%) in favor.

The ratification of a previous option allotment faced similar opposition.

The employee option plan was passed with 37,331,387 proxy votes (79.5%) in favor, 9,644,232 proxy votes (20.5%) against and 126,730,888 votes excluded or abstaining. Three million proxy votes were cast against the re-election of Elmar Schnee as a director, but Dr George Morstyn was re-elected overwhelmingly.

Chemgenex most recent Appendix 3B share issue announcement said there were 283,348,870 shares on issue, meaning that opposition to the resolutions came from 3.4 percent of all shares on issue.

Chemgenex was up half a cent or 1.1 percent to 45.5 cents.

<u>ITL</u>

Dr Jagmohanbir Singh Dillon has failed to become a director of ITL.

In August 2010, ITL said that co-founder William Leonard Mobbs and Sanjay Sehgal had been appointed as directors replacing Roy Rose and chief executive officer Brian Andrews who resigned as chief executive officer "effective immediately and has been placed on garden leave" (Aug 24, 2010).

The company said at that time, Mr Mobbs would act as interim chief executive officer while a replacement was found and a notice of shareholder requisitioned meeting received by the company on August 3, 2010, had been withdrawn.

Dr Mike Hirshorn resigned as an ITL director on August 11 and the following day, ITL told the ASX of the meeting requisitioned to consider the election of Dr Jagmohanbir Singh Dillon as a director (BD: Aug 11, 12, 2010).

Today, Dr Dillion's election was defeated with 45,550,962 votes against and 18,379,790 votes in favor.

Sanjay Sehgal and William Mobbs were elected with 15.9 million votes against and 50.3 million votes in favor.

Julian Gosse was reelected with a slightly smaller margin.

ITL was untraded at 5.6 cents.

<u>ACUVAX</u>

UBS AG and related bodies have ceased their substantial holding in Acuvax. In their last substantial shareholder notice UBS and the related bodies increased their investment in Acuvax from 51,470,000 shares (6.82%) to 51,980,000 shares but were diluted to 5.52 percent (BD: Oct 14, 2010).

UBS AG said the holdings were held by its London Branch and related to a prime broking agreement.

Acuvax was untraded at 0.2 cents.