

Biotech Daily

Wednesday November 18, 2009

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: TISSUE THERAPIES UP 10%; BENITEC DOWN 9%
- * TISSUE THERAPIES CLAIMS 'OUTSTANDING' VITROGRO ULCER RESULTS
- * MESOBLAST '6-MONTH IMPROVEMENT IN HEART MUSCLE FUNCTION'
- * STARPHARMA RAISES \$16m FOR BACTERIAL VAGINOSIS TRIAL
- * NEUREN RAISES \$8m FOR PHASE II TRAUMATIC BRAIN INJURY TRIAL
- * FERMISCAN ADMINISTRATORS APPOINTED
- * PRIMA TO DEVELOP ORAL CERVICAL CANCER VACCINE
- * AVEXA LOSES 4-MONTH DIRECTOR LAWRENCE GOZLAN
- * MODEST DISSENT AT AVEXA AGM
- * UP TO 23.5% DISSENT AT CLINUVEL AGM
- * GOODBYE MEDICAL THERAPIES; G'DAY CELLMID
- * EASTLAND APPOINTS CALVIN ROSS DIRECTOR

MARKET REPORT

The Australian stock market climbed 0.2 percent on Wednesday November 18, 2009 with the S&P ASX 200 up 9.6 points to 4,739.0 points. Sixteen of the Biotech Daily Top 40 stocks were up, six fell, nine traded unchanged and nine were untraded.

Tissue Therapies was best, up 1.5 cents or 9.7 percent to 17 cents with 1.8 million shares traded, followed by Impedimed up 9.6 percent to 80 cents. Viralytics climbed 7.7 percent; Genetic Technologies and Heartware were up more than three percent; Biota, Chemgenex, Circadian, Prana and Universal Biosensors rose more than two percent; with Acrux, Clinuvel, Genera, Mesoblast and Nanosonics up more than one percent.

Benitec led the falls, down 0.4 cents or 9.1 percent to four cents with 93,667 shares traded, followed by Optiscan down 6.7 percent to 9.8 cent. Bionomics and Tyrian lost more than five percent; Avexa fell 4.55 percent; with Alchemia, Cellestis, Cochlear, CSL, Pharmaxis and Phosphagenics down more than one percent.

TISSUE THERAPIES

Tissue Therapies says its Canadian diabetic ulcer wound treatment trial has produced "outstanding results".

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that one of the 10 patients in the completed trial, a 37-year old woman, had a non-healing ulcer which was treated with the company's Vitrogro for eight weeks, resulting in a 74 percent reduction in ulcer area.

Dr Mercer said another patient, a 73-year old male tobacco smoker, had been the subject of doctors' discussions regarding the amputation of the front half of his foot.

Dr Mercer said the patient had been completely unresponsive to any treatment for two years, but one low-dose treatment of Vitrogro once a week for six weeks resulted in 29 percent ulcer healing.

Dr Mercer said that eight patients in the company's Freemantle, Western Australia trial had completed therapy, with results on four more to be finalized by the end of this year (BD: Jan 19, 2009).

He said Vitrogro should be registered and on sale outside the US market in 2011. "This really places us in an excellent position to pursue term sheet negotiations with our short list of potential commercial partners," Dr Mercer said.

In a media release to the ASX Dr Mercer said Vitrogro "had one again produced excellent clinical results in medically complex patients with chronic skin wounds".

"In my experience, these ulcer healing results are exceptional", Dr Mercer said. Tissue Therapies was up 1.5 cents or 9.7 percent to 17 cents with 1.8 million shares traded.

MESOBLAST

Mesoblast says the first patients to receive Revascor off-the-shelf adult stem cells for heart failure show "sustained improvement in heart muscle function at six months". Mesoblast said the interim phase II trial results were presented at the annual conference of the American Heart Association in Orlando, Florida.

Mesoblast said the trial, run by its sister company Angioblast, compared three doses of Revascor against standard of care in up to 60 patients with moderate to severe congestive heart failure, defined as a baseline ejection fraction of 40 percent or lower.

Each dose was tested in a group of 20 patients, randomized three treated patients to one control patient and results from the first group of patients receiving the lowest dose of Revascor were presented to the conference by lead investigator Dr Nabil Dib.

Mesoblast said patients who received a single injection of Revascor into damaged heart muscle had significantly improved cardiac function at both three and six months compared with baseline. At six months, a single dose of Revascor was accompanied by a 22 percent mean increase in ejection fraction, whereas controls had an 18 percent mean decrease in ejection fraction over the same time period.

There were no cell-related adverse events and the observed improvement between treated and control patients above medical standard of care was more than two-fold higher than previously reported with existing device therapies, Mesoblast said. Mesoblast said Revascor was delivered to damaged areas of the heart by a minimally invasive cardiac catheterization procedure performed under local anaesthesia while the patient was awake who were released from the hospital within 24 hours.

Mesoblast said 40 patients had been treated, with the final group of 20 patients evaluating the highest dose of Revascor expected to complete enrolment in early 2010.

Mesoblast was up 2.5 cents or 1.8 percent to \$1.42.

STARPHARMA

Starpharma has raised \$15.6 million through a placement of 30 million shares at 52 cents per share to institutional and sophisticated investors.

Starpharma said that with the placement proceeds it had cash reserves of \$24 million.

The company said existing Starpharma shareholder Orbis Investment Management was the lead investor and its largest shareholder Acorn Capital also participated in the raising, along with several other existing and new institutional investors.

Starpharma said the placement was "significantly oversubscribed" and was managed by Shaw Corporate Finance.

The company said the funds would be used to finance a clinical trial program to develop Vivagel for the treatment of bacterial vaginosis and to further strengthen the balance sheet for future development and partnering opportunities.

Starpharma chief executive officer Dr Jackie Fairley said the funds would "progress Vivagel as a [bacterial vaginosis] treatment through to the completion of phase III clinical trials to support licencing to a major marketing partner".

The company said bacterial vaginosis was the most common vaginal infection with more than 21 million US women suffering from the infection and the global market for treatments was about \$US300-\$350 million.

Starpharma was unchanged at 60 cents.

NEUREN

Neuren will place up to \$6.7 million in convertible notes with Springtree Special Opportunities Fund, pending shareholder approval and raising \$US1 million (\$1.08 million) from other sources.

Neuren said New York's Springtree had advanced \$550,000 under an initial note and Neuren issued Springtree 5,900,000 options exercisable at 4.45 cents within four years after the execution of the agreement, 6,000,000 shares by way of collateral for repayment of the amounts advanced and 8,070,669 shares in satisfaction of its obligation to pay Springtree a commitment fee. The shares issued as collateral may be cancelled or purchased at the discretion of Springtree.

Neuren said it would call a special meeting of shareholders and provide additional details on the terms of the agreement which require Springtree to advance under additional notes monthly over 24 months beginning with the first tranche at \$400,000, the next 10 tranches at \$100,000, and subsequent tranches at \$60,000.

Neuren said the placement was arranged by KTA Capital, a New York investment bank and broker-dealer registered with the US Securities and Exchange Commission. Neuren said it had commitments for investment of \$US1 million from existing and new shareholders note, pending shareholder approval.

The investment could be a placement in Neuren shares, acquisition of a direct interest in the company's US subsidiary Neuren Pharmaceuticals or a combination of the two. Springtree managing director Jeff Easton said his company was "impressed with the creative and cost-effective strategies that the company has employed to maintain the momentum of development for their lead candidates ... under difficult market conditions". "Neuren clearly brings great passion to pursuing development of products for traumatic brain injury and other major unmet medical needs," Mr Easton said.

Neuren chief executive officer Larry Glass said the funds would "support the company's operations, providing the resources needed to complete the NNZ-2566 phase II trial with the US Army, as well as to explore additional opportunities for the remaining pipeline". Neuren fell 1.1 cents or 21.6 percent to four cents with 7.2 million shares traded.

FERMISCAN

Fermiscan director Mark Fordree says Giles Geoffrey Woodgate of Woodgate & Co chartered accountants has been appointed the company's voluntary administrator. Fermiscan said the administrator would contact creditors of these companies as part of the administration and explain the process and likely timeframe of the administration. The company said that any off-market transfer of shares would be void, except if the transfer was with the administrator's or Court's consent.

Fermiscan recently lost its appeal to the New South Wales Supreme Court in its long-running legal battle with the inventor of its x-ray diffraction of hair test, Prof Veronica James (BD: Nov 11, 12, 2009).

Fermiscan last traded at three cents.

PRIMA BIOMED

Prima has engaged the Universities of New South Wales and Queensland to begin a research program to develop an oral delivery system for cervical cancer vaccines. Prima said the development of an oral delivery system for cervical cancer vaccines was "potentially a major breakthrough in drug delivery for cervical cancer treatment as it provides a suitable large scale alternative method of drug delivery to injection". Prima's said the research program would lead to the development of a widely available, cost effective oral cervical cancer vaccine, "a prime opportunity for the company to significantly increase the level of inoculation for cervical cancer worldwide which will have significant benefit for mass inoculation environments such as third world countries". Prima said the University of New South Wales and the University of Queensland would undertake the research program with the Diamantina Institute for Cancer at the University of Queensland under Prof Ian Frazer, who developed the Gardasil vaccine marketed by CSL and Merck Sharpe & Dome, along with Prof Neil Foster and the Supercritical Fluids Department at the University of New South Wales.

Prima said it was finalizing plans for its US Food and Drug Administration-approved pivotal phase IIb trial of CVac for ovarian cancer.

Prima was unchanged at 16.5 cents.

<u>AVEXA</u>

Avexa says Lawrence Gozlan has resigned as a director "due to increased commitments in [his] capacity as a fund manager and board member of other entities".

Mr Gozlan was appointed to the board on June 30, 2009.

Mr Gozlan is the chief executive officer and founder of life science investment fund Scientia Capital.

Avexa fell one cent or 4.55 percent to 21 cents with 4.2 million shares traded.

AVEXA

Up to 13 percent of Avexa shareholders opposed resolutions at Avexa's annual general meeting.

Avexa's remuneration report was opposed by 16,340,720 proxy votes (13.16%) with 107,871,193 proxy votes (86.84%) with the ratification of a prior share issue opposed by 8.4 percent of proxy votes, with the reelection of director Joe Baini supported by more than 120 million proxy votes and opposed by 5.58 million proxy votes.

CLINUVEL

A significant minority of Clinuvel shareholders opposed a performance rights plan, the remuneration report and the reelection of director Dr Helmer Agersborg.

Clinuvel's conditional performance rights plan was opposed by 4,845,202 proxy votes (23.5%) with 15,759,294 proxy votes (76.5%) in favor

The reelection of Dr Agersborg and the remuneration report were supported by more than 16.9 million votes, with more than 3.3 million votes against.

Director Stanley McLiesh was elected overwhelmingly.

Clinuvel was up half a cent or 1.8 percent to 28.5 cents with 1.1 million shares traded.

CELLMID, MEDICAL THERAPIES

Medical Therapies says shareholders have approved its name change to Cellmid Limited, which is effective immediately.

The company said it would trade under the ASX code of CDY from the opening of the stock market on November 20, 2009.

The company said the new name reflected its main operating business; the commercialization of intellectual property around the novel target, midkine, a cell signaling agent.

Cellmid said its diagnostic and therapeutic products related to the cell signaling function. The company said the technology was developed by Japan's Cell Signals Inc and the name pays homage to the Cell Signals researchers "for their years of commitment in developing this outstanding technology".

Cellmid (formerly Medical Therapies) was untraded at 2.8 cents.

EASTLAND MEDICAL SYSTEMS

Eastland has appointed Calvin Ross as a non- executive director effective from November 20, 2009 following the company's annual general meeting.

Eastland said Mr Ross was a specialist drug delivery scientist with extensive experience in the pharmaceutical industry particularly the therapeutic areas of malaria, pain management and drug addiction.

The company said he was "a leading authority in the development of sublingual aerosol and spray formulations and device design".

Mr Ross is the founder and research and development director of Protopharma and has held senior research and development roles with Bespak Plc, Sosei Group, Dallas Burston Group, Terumo and Bioglan Plc.

Eastland fell 0.3 cents or 3.95 percent to 7.3 cents.