Biotech Daily

Monday November 25, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANTEO UP 27%, CELLMID DOWN 17%**

*** MESOBLAST, REGENEUS WELCOME JAPAN PHASE II APPROVAL LAW**

*** LIVING CELL EARNS $2m ON NTCELL PARKINSON'S IMPLANT APPROVAL**

*** NOVOGEN, CANTX TRILEXIUM 'DESTROYS OVARIAN CANCER SPHERES'**

*** 32% OF STARPHARMA AGM OPPOSED WITHDRAWN CONSTITUTION**

*** AVITA 75% REMUNERATION 1st STRIKE**

*** UP TO 29% OF UNILIFE OPPOSE DIRECTOR SHARES**

*** ALLIED HEALTH FORMALLY RENAMED ADMEDUS**

*** BIOXYNE PLACEMENT, OPTIONS EGM**

MARKET REPORT

The Australian stock market climbed 0.32 percent on Monday November 25, 2013 with the S&P ASX 200 up 16.9 points to 5,352.8 points. Fourteen Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and three were untraded. All Big Caps were up.

Anteo was the best, up 3.5 cents or 26.9 percent to 16.5 cents with 28.1 million shares traded, followed by Prima up 17.1 percent to 4.8 cents with 35.8 million shares traded and Neuren up 11.5 percent to 14.5 cents with 14.3 million shares traded.

Phosphagenics climbed 8.3 percent; Patrys, Phylogica and Viralytics were up more than five percent; Universal Biosensors was up 4.8 percent; Compumedics was up 3.45 percent; Mesoblast, Sirtex and Tissue Therapies rose more than two percent; Acrux was up 1.2 percent; with Cochlear, CSL, Prana and Resmed up by less than one percent.

Cellmid led the falls, down 0.7 cents or 17.1 percent to 3.4 cents with 19.3 shares traded followed by Antisense down 14.7 percent to 14.5 cents with 359,051 shares traded.

Avita lost 9.1 percent; Genetic Technologies fell 7.25 percent; Benitec, Circadian and Living Cell were down more than four percent; Admedus and IDT were down more than three percent; Atcor and Ellex shed more than two percent; Bionomics, Clinuvel and Osprey were down more than one percent; with GI Dynamics and Reva down by less than one percent.

MESOBLAST

Mesoblast says Japan has enacted a Bill providing for accelerated approval of stem cell products with approval based on safety alone, potentially with a phase II trial.

Mesoblast said that Japan was “the world's second-largest mature healthcare market” and the legislation revised the existing Pharmaceutical Affairs Law to define new medical products containing stem cells to be termed regenerative medicine products.

The company said that the legislation allowed Japan to give conditional approval to the products if their safety was confirmed in phase II clinical trials.

In an interview on ABC-TV Mesoblast chief executive Prof Silviu Itescu said that “providing that in phase II trials they demonstrate sufficient safety signals, and of course safety trials are not usually designed to statistically prove efficacy, that such products might be approved in the Japanese market, without actually having to do phase III trials”.

“That’s a very exciting prospect for us,” Prof Itescu said. “It potentially shaves off several years and very large expenditures in getting our products into the Japanese market.”

Prof Itescu said Korea had a similar law and the said the US had its ‘Breakthrough Designation’ to expedite approvals.

Mesoblast said that the new Japanese legislation opened a pathway to commercialize its mesenchymal lineage stem and precursor cell products within a significantly shorter timeframe.

The company said that it intended to establish strategic partnerships for its suite of products to facilitate earlier Japanese regulatory approvals and commercial launches.

Mesoblast said that its first partnership in Japan was with JCR Pharmaceuticals, through its Osiris acquisition, for its culture-expanded mesenchymal stem cell product for steroid refractory graft-versus-host disease.

The company said that JCR intended to file for Japanese marketing approval of its mesenchymal stem cell product JR-031 by April 2013 under the existing regulatory framework and if successful, JR-031 would be the first allogeneic or off-the-shelf cell-based product approved in Japan.

Mesoblast was up 16 cents or 2.7 percent to $6.02 with 661,163 shares traded.

REGENEUS

Regeneus said that it also welcomed the new Japanese law, providing a separate approval channel for regenerative medicine products like cell therapies.

Regeneus said that once a company “demonstrated limited safety and efficacy data in humans, the new cell therapy can be approved for commercial use with data reporting requirements and potential for national insurance coverage”.

Regeneus chief executive officer Prof Graham Vesey said the new legislation “provides us with a well defined pathway to fast-track the clinical trial and potential approval of our new human off-the-shelf cell therapy to treat osteoarthritis and other inflammatory musculoskeletal conditions”.

Prof Vesey said that the off-the-shelf Cryoshot had been used to treat more than 2000 dogs and horses with osteoarthritis in extensive field trials in Australia.

“The results have been very encouraging and we anticipate the canine Cryoshot product entering into an FDA approved trial for canine osteoarthritis in 2014,” Prof Vesey said.

Regeneus said that human Cryoshot used donor adipose or fat-derived mesenchymal stem cells, and once injected into an arthritic joint, the stem cells used in Cryoshot “seek to embed at the site of inflammation and secrete a range of cytokines which encourage a reduction of inflammation and repair and regeneration of the damaged tissue”.

Regeneus climbed 10.5 cents or 21.1 percent to 60 cents with 2.1 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says the independent data safety monitoring board has approved three more patients in its phase I/IIa trial of NTCell for Parkinson's disease.

Living Cell said that the board reviewed the safety data from the initial patient in the Auckland City Hospital phase I/IIa clinical trial and said that implants of the encapsulated pig choroid plexus brain cells could proceed (BD: Sep 20, 2013).

The company said that the phase I/IIa trial was an open label investigation of the safety and clinical effects of NTCell in four patients diagnosed with Parkinson's disease for at least five years.

Living Cell managing director Dr Andrea Grant said the initial safety data from the clinical trial was "consistent with that documented in the preclinical trial with non-human primates which was recently published in the Journal of Parkinson's Disease" and the first patient was "well, all things considered".

Living Cell said that the data safety monitoring board "primarily considered safety data obtained from the first patient implanted with NTCell in September".

"The first opportunity we will have to obtain an indicative assessment efficacy will be when all four patients complete six months of follow-up post their first implant." Dr Grant said.

Living Cell said that NTCell for Parkinson's disease was a co-development with Japan's Otsuka Pharmaceutical Factory and Living Cell expected a second cash payment of $2 million from Otsuka as a result of the DSMB authorization, in addition to the $3 million received for the option to license NTCell.

Living Cell said that Otsuka was funding all the research and development costs of with the phase I/IIa clinical trial, estimated at $2.1 million, providing both income and funding for the ongoing clinical development of NTCell in Parkinson's, provided the trial meets its endpoints.

Living Cell fell half a cent or 4.55 percent to 10.5 cents with 2.6 million shares traded.

NOVOGEN

Novogen says that its US 85 percent subsidiary Cantx has found that lead drug candidate Trilexium is highly effective at destroying ovarian cancer spheroid architecture.

Novogen chief scientific officer Dr David Brown said the result was an "important step forward in predicting the likely success of Trilexium in-vivo and in the clinic in particular".

"Spheroids are mini-tumors and the ability of Trilexium to penetrate and to kill these tumor cell structures is a significant step forward for this drug," Dr Brown said.

The company said that researchers at Yale University had shown that cancer stem cells isolated from the tumors of ovarian cancer patients were able to form self-renewing spheroids, regarded as a three-dimensional model of ovarian cancer in the test tube.

Novogen said that when injected into a mouse model, the spheroids formed highly vascularized tumors mirroring that of the human disease.

Novogen collaborator Yale Medical School's Prof Gil Mor said that "in terms of drug discovery, these three-dimensional structures serve as a robust screen to identify drug candidates worth progressing into expensive animal studies".

"They come directly from drug-resistant tumors and standard-of-care drugs such as paclitaxel and carboplatin have no effect on them," Prof Mor said.

"Trilexium is the first drug in our hands that has been shown to penetrate and destroy the spheroid architecture," Prof Mor said.

"This observation demonstrates that Trilexium can diffuse into the spheroid and gives us confidence that it should be able to kill ovarian cancer tumors in vivo," Prof Mor said.

Novogen was up 3.5 cents or 15.9 percent to 25.5 cents with 15.3 million shares traded.

STARPHARMA HOLDINGS

Starpharma's withdrawn constitution resolution including a reduction in the maximum board size was opposed by 31.9 percent of annual general meeting votes.

On Friday, Starpharma said that the opposition was led by two proxy advisors concerned about the proposed reduction in the maximum size of the board from 15 to seven directors (BD: Nov 22, 2013).

After the market closed on Friday, Starpharma posted the meeting's proxy votes showing that 47,978,665 votes (31.9%) opposed the changed constitution with 102,318,066 votes (68.1%) in favor.

The re-election of director Richard Hazleton was opposed by 28,951,039 votes (19.2%) with 121,871,442 votes (80.8%) in favor, while Peter Bartels was re-elected with more than 147.8 million votes in favor and 2.99 million votes against.

The meeting approved the issue of 950,000 conditional 'performance rights' to chief executive officer Dr Jackie Fairley with 132,822,054 votes (90.5%) in favor and 14,005,728 votes (9.5%) against.

The remuneration report was supported by 133.8 million votes and opposed by 12.5 million votes.

The company's most recent Appendix 3B new issue announcement said that Starpharma had 284,164,948 shares on issue, meaning that the 47,978,665 votes against the constitution amounted to 16.9 percent of the company, sufficient to requisition extraordinary general meetings.

Starpharma was unchanged at 88.5 cents.

AVITA MEDICAL

Avita's annual general meeting voted strongly against the remuneration reports with a poll showing 80,523,745 votes (75.22%) against and 26,532,311 shares (24.78%) in favor.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

Avita's most recent Appendix 3B new issue announcement said that the company had 325,308,404 shares on issue, meaning that the 80,523,745 votes against the remuneration report amounted to 24.75 percent of the company.

According to Avita's 2013 annual report, chief executive officer Dr Bill Dolphin received a fixed remuneration of $343,868 for the year to June 30, 2013, along with a short term incentive of $103,285 in cash as well as other payments.

The annual report said that the company's seven directors received salary and fees totaling $256,385 and six key management personnel earned a total of $848,959 for the year to June 30, 2013.

A resolution to approve the company's 10 percent placement capacity was opposed by 7.2 million shares and supported by 95.7 million shares,

Director Mike Perry was elected with 88.8 million votes in favor and 4.1 million votes against, with founder Prof Fiona Wood re-elected overwhelmingly.

Avita fell one cent or 9.1 percent to 10 cents with 1.8 million shares traded.

UNILIFE

Unilife says its annual general meeting voted dissent against the grant of director shares and chief executive officer Alan Shortall will replace Slavko Bosnjak as chairman.
The resolutions, to provide 105,000 US shares to directors Mr Bosnjak, Jeff Carter, William Galle, John Lund, Mary Wold and a further 52,500 shares to Mr Galle were opposed by about 11.4 million votes to 30.4 million votes.
The Unilife announcement provided a Computershare proxy report that described the election of directors as either 'for' or 'withheld' with the strongest dissent 4,381,120 votes (10.36%) 'withheld' in the election of Mr Bosnjak and 37,893,553 votes (89.64%) in favor.
Mr Carter faced 9.52 percent of votes withheld while directors Mr Galle, Mr Lund and Ms Wold faced more than five percent 'withheld' and Mr Shortall had 6.6 percent of votes 'withheld'.
The executive compensation package was opposed by about 14 percent of the vote.
The company's most recent Appendix 3B new issue announcement said that Unilife had the equivalent of 602,118,138 Chess depositary interests on issue, meaning that the largest opposition vote against Mr Carter's shares of 11,683,867 votes equivalent to 70,103,202 Australian shares amounted to 11.6 percent of the company, sufficient to requisition extraordinary general meetings.
Unilife was up 6.5 cents or 9.6 percent to 74 cents with 2.8 million shares traded.

ADMEDUS (FORMERLY ALLIED HEALTHCARE GROUP)

Admedus formally began trading under its new name today but retaining the Allied Health ASX code of AHZ.
Admedus fell half a cent or 3.1 percent to 15.5 cents with 9.5 million shares traded.

BIOXYNE

Bioxyne shareholders will vote on resolutions relating to the transaction funding for the failed acquisition of Vitality Devices earlier this year (BD: Feb 18, May 23, 2013).
Bioxyne said that despite the termination of the proposed acquisition "there remain certain commitments emanating form the transaction funding placement" which raised $508,371 at 2.2 cents a share with one-for-two free attaching options exercisable at four cents by March 31, 2015.
The resolutions to the meeting include the payment of shares in lieu of directors' fees to chairman Tony Ho and directors Patrick Ford and Jeremy Curnock Cook, as well as shares in lieu of fees to chief executive officer Dr Phillip Comans.
Other resolutions relate to the placement as well as shares and options to an associate of Mr Ford.
The meeting will be held at the Institute of Chartered Accountants, Level 1, 33 Erskine Street, Sydney, on December 21, 2013 at 10am (AEDT).
Bioxyne was untraded at half a cent.