Biotech Daily

Wednesday November 28, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BIONOMICS UP 7%, GENETIC TECHNO DOWN 24%**

*** EDITORIAL: MERVYN, MERVYN, MERVYN !**

*** STARPHARMA VIVAGEL FAILS PHASE III; FDA NDA ON HOLD**

*** ALLIED'S CARDIOCEL SHEEP TRIAL GROWS NEW TISSUE**

*** BIOXYNE TO LET SHAREHOLDERS DECIDE HI-1640V'S FATE**

*** GENETIC TECHNOLOGIES APPOINTS DR MAL BRANDON CHAIRMAN**

*** CONSEGNA LOSES DIRECTOR BRENDAN FLEITER, BELT-TIGHTENING**

*** HEALTHLINX 27% AGM DISSENT AGAINST DIRECTOR NICK GATSIOS**

*** NUSEP LOSES 3 DIRECTORS AHEAD OF 2nd STRIKE AGM**

*** GI DYNAMICS RELEASES 90.5m ESCROW SHARES**

MARKET REPORT

The Australian stock market fell 0.21 percent on Wednesday November 28, 2012 with the S&P ASX 200 down 9.5 points to 4,447.3 points.

Seven of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and nine were untraded.

Bionomics was the best, up two cents or seven percent to 30.5 cents with 234,166 shares traded.

Avita, GI Dynamics and Mesoblast climbed four percent or more; Sunshine Heart was up 3.2 percent; Sirtex rose 2.7 percent; Resmed and Viralytics were up more than one percent; with CSL up 0.6 percent.

Genetic Technologies led the falls, down 2.1 cents or 24.1 percent to 6.6 cents with 6.4 million shares traded.

Antisense lost 8.3 percent; Cellmid was down 6.25 percent; Impedimed and Tissue Therapies fell more than four percent; Living Cell, Phosphagenics and QRX were down more than three percent; Bioniche, Nanosonics, Prana and Psivida shed more than two percent; with Alchemia, Acrux and Optiscan were down more than one percent.

EDITORIAL: GENETIC TECHNOLOGIES

To lose one competent board and management team may be considered misfortune, to lose two looks like carelessness (Oscar Wilde, Sir Humphrey Appleby).

Just when the investors were beginning to think it was safe to take the Genetic Technologies waters, founder and former chief executive officer Dr Mervyn Jacobson decided to make his mark on his company and roll the recently appointed and very respected chairman, Dr Mel Bridges.

After all the work former (as of yesterday) chief executive officer Dr Paul MacLeman had put into making Genetic Technologies an upstanding Biotech Daily Top 20 company, following the last abysmal board dismissal by Dr Jacobson in 2008, with sales and reimbursement underway in the US, licencing deals – in part effected by Dr Jacobson – and a focus on a growing company beginning to attract the attention of the wider non-biotech investment market, Mervyn exercised his very large holding in the company, ejected its chairman, leaving Dr MacLeman, who recruited Dr Bridges, nowhere to go but out the door, immediately followed by director Greg Brown and the head of legal and corporate Dr David Sparling.

As the company and shareholders were taken by surprise, so was the market and other observers, although Biotech Daily has warned consistently of the perils of owner drivers (BD: Sep 19, 2008).

In 2008 the Genetic Technologies issue appeared to revolve around the recovery of licencing fees related to BRCA testing for breast cancer and Dr Jacobson spilled the board of chairman Henry Bosch, chief executive officer Michael Ohanessian, who previously ran Vision Biosystems, with directors including former Federal Treasurer John Dawkins, David Carruthers and Monash University deputy chancellor Dr Leanne Rowe.

Biotech Daily said at that time that that “Mervyn can either have 42% of a 10 cent a share company or 19.95 percent of a $1.30 a share company”.

Following that last purge, Genetic Technologies fell to 2.8 cents, with Dr MacLeman taking it to a high of 35 cents. The share price has fallen back to around 10 cents, with a few of the usual biotechnology industry delays, but there was promise of strength ahead.

Yesterday’s intended purge of Dr Bridges, with a possibly unintended but obvious consequence of the loss of Dr MacLeman as well as Mr Brown and Dr Sparling and perhaps others to follow, is simply unfathomable.

This morning, RBS Morgans’ Scott Power, who had been warming to the Genetic Technologies story, declared the stock “move to Sell - sub investment grade” and in The Australian’s Criterion column Tim Boreham said it was a “train smash” to be avoided.

Today, Mervyn has 29 percent of a 6.6 cents a share company and it is hard to imagine who would want to join his board or take on the role of chief executive officer and chief executive Mervyn manager.

David Langsam
Editor

STARPHARMA HOLDINGS

Starpharma says that Vivagel has failed to meet its phase III trial primary endpoint for clinical cure in the treatment of bacterial vaginosis.

Starpharma said that the two phase III studies of 1% SPL7013 Gel or Vivagel for the treatment of bacterial vaginosis showed that Vivagel "achieved statistically significant clinical cure and resolution of patient-reported symptoms of [bacterial vaginosis] at the end of treatment visit (two to five days post treatment)"

"However, the primary endpoint of clinical cure two to three weeks after the cessation of treatment was not met," Starpharma said.

The company said that a new drug application for Vivagel for the treatment of bacterial vaginosis would not be filed with the US Food and Drug Administration at this time due to the lack of statistical significance at the two to three week 'test of cure' visit, although other claim strategies such as symptomatic relief and other regulatory jurisdictions could be available and would be fully explored.

Starpharma said that although not sustained for the full two to three weeks after cessation of therapy, the highly statistically significant clinical cure achieved with Vivagel compared with placebo gel at the end of treatment at two to five days after the end of treatment, confirmed, in the large scale clinical studies, that Vivagel could have a significant impact in the treatment and management of bacterial vaginosis.

The company said that each study enrolled about 250 women and in each study 50 percent and 57 percent of women, respectively, achieved clinical cure with Vivagel compared to 17 percent and 21 percent with placebo ($p < 0.001$) at end of treatment.

At the two to three weeks 'test of cure', the clinical cure rates for Vivagel and placebo were 27 percent versus 21 percent, respectively, in trial SPL7013-015 and 28 percent versus 28 percent in trial SPL7013-016.

The company said that vaginal discharge was resolved in 71 percent and 74 percent of women respectively compared to placebo ($p < 0.001$), 61 percent and 68 percent of participants reported absence of abnormal vaginal discharge ($p = 0.033$; $p < 0.001$), vaginal odor, as assessed by the clinician in a 'whiff' test was resolved in 72 percent and 70 percent of women respectively ($p < 0.001$) at end of treatment, while 76 percent and 72 percent of participants reported resolution of unpleasant vaginal odor ($p < 0.001$).

The company said that the results were "entirely consistent with the strategy being pursued to address prevention of recurrence of [bacterial vaginosis], for which ongoing therapy every second day with Vivagel is intended to achieve a reduced risk of recurrence of the condition".

Starpharma said that the demonstration of statistically significant clinical cure at end of treatment, the key secondary endpoint of the studies, was "highly supportive of Vivagel for prevention of recurrence of [bacterial vaginosis], and there is no negative impact of these phase III results on the investigation of the product for this indication".

The company said that the phase II study of Vivagel (SPL7013-014) for prevention of recurrence of bacterial vaginosis was ongoing, with results expected by April 2013.

Starpharma said that the phase III results at test of cure were in contrast to the 2011 phase II bacterial vaginosis treatment study in which highly statistically significant clinical cure was achieved for Vivagel 1% at both end or treatment and test of cure.

The company said there appeared to be "several potentially confounding factors in the phase III studies, including unusually high placebo clinical cure rates at some sites, and the fact that these placebo cure rates increased between the two time points, rather than decreased, and both factors could have contributed to the inability to achieve the required primary endpoint and reproduce the phase II results.

Starpharma was in a trading halt and last traded at $1.62.

ALLIED HEALTHCARE GROUP

Allied says a study of its Cardiocel to reconstruct sheep heart valves showed “outstanding performance … in the reconstruction of heart valves compared to the control”.

Allied said that its Adapt-treated bovine cardiovascular patches promoted healing at the site of repair and other benefits including reduced calcification compared to the control, as well as minimal thickening of the tissue.

The company said that the histology data showed that after eight months there had been significant new tissue growth on both sides of the implanted Cardiocel patch, consisting of collagen and several different cell types, which were typically found in a healthy cardiovascular healing process as well as in heart valves.

Allied said that the study found no evidence of macroscopic calcification of the Cardiocel implant on echocardiography, or heart ultrasound, and in molecular measurement of extractable calcium, the active Cardiocel tissue had 40 percent less calcium than the control native autologous tissue.

Allied group managing director Lee Rodne said the results were “remarkable, particularly regarding evidence that the Cardiocel patch material appears to enable tissue regeneration, opening up the possibility for Cardiocel treated valves to regenerate without additional intervention or assistance”.

“The demonstration of effective tissue regeneration without adding external stimulation like stem cells or growth factors is a major new finding from this study,” Mr Rodne said.

Allied said that the histology results were independently assessed by Harvard Medical School Department of Pathology’s Prof Frederick J Schoen and calcification levels were independently quantified by the Murdoch University research group.

Allied reported that in his conclusion, Prof Schoen said that “no apparent significant adverse effects were present”.

“Cardiocel pericardium appears to be a suitable bio-prosthetic substitute for valve reconstruction procedures and consideration as an alternative to autologous pericardium,” Prof Schoen said.

Allied’s regenerative medicine chief executive officer Bob Atwill said that as well as tissue regeneration, further evidence of the lack of calcification was “very encouraging”.

“Reduced calcification should result in the reduction of repeat surgeries, and therefore the reduction in unnecessary patient risk, stress and cost, promoting a lifelong solution for patients,” Mr Atwill said.

Allied said that the Cardiocel scaffold appeared to attract endogenous stem cells which allowed normal cell growth, proliferation and differentiation into fully functional valve tissue and research indicated that a tissue matrix became incorporated into native tissue.

The company said the results showed that Cardiocel became enveloped with endothelial cells via normal cell growth, suggesting it was invisible to the recipient immune system and became native tissue over time and opened opportunities for additional Adapt products.

The company said that independent validation of the results confirmed the regenerative performance of the Adapt-treated tissue and provided an opportunity to transform valve reconstructive surgery, along with expanding opportunities in congenital heart disease repair surgery.

“These regenerative results, in one of the most challenging models, are significant as native tissue has regenerated after eight months,” Mr Atwill said.

“From a commercial perspective, as Cardiocel is a class III medical device, it has a much more straightforward and cost effective route to market compared to biologic agents and stem cells that are targeting cardiac repair,” Mr Atwill said.

Allied was unchanged at 2.3 cents with 6.2 million shares traded.

BIOXYNE

Bioxyne says an annual general meeting resolution providing equity to Vaxine has been withdrawn and an extraordinary meeting will decide whether to further develop HI-164OV.
Following the failure of HI-165OV to meet its chronic obstructive pulmonary disease phase IIb trial endpoints, major shareholder Octa Phillips and later Phillip Comans called for the replacement of directors but the bid failed (BD: Jun 28, Aug 27, 31, Oct 25, 30, 2012).
In September, Bioxyne announced a heads of agreement with the Adelaide-based Vaxine, to develop a study to continue investigation into the effectiveness of HI-164OV on a selected group of patients with chronic obstructive pulmonary disease (BD: Sep 24, 2012).
Today Bioxyne said it had in-principle agreement with Vaxine for the study protocol and process.
The company said the proposed funding for the study involved the issue of equity to Vaxine, subject to shareholders' approval.
Bioxyne said that shareholders would "have the opportunity to participate in the decision as to whether the proposed study with the HI 164 asset to continue, or, to cease development of HI 164 and pursue alternative opportunities".
The company said that shareholders would be asked to approve a capital raising of up to $2.0 million to provide working Bioxyne said the notice of meeting was scheduled for dispatch later this week with meeting to be held early in January 2013.
Bioxyne was untraded at three cents.

GENETIC TECHNOLOGIES

Genetic Technologies has appointed Dr Mal Brandon as chairman and chief operating officer Alison Mew as acting chief executive officer.
Dr Brandon said the board was "confident that the company will continue to build on the solid foundation that has been created and looks forward to further expansion of its US operations and its global licensing programs".
Separately, Genetic Technologies said that 45 percent subsidiary Immunaid would become an unlisted public company "so that it may now grow rapidly and receive additional investment capital".
Genetic Technologies founder Dr Mervyn Jacobson is the chief executive officer of Immunaid.
Genetic Technologies fell 2.1 cents or 24.1 percent to 6.6 cents with 6.4 million shares traded.

CONSEGNA

Consegna says director Brendan Fleiter will not stand for re-election at the annual general meeting and the company will cut costs, including chairman Fabio Panunuti's pay.
Consegna said that Mr Fleiter had resigned "to dedicate more time with his other directorships including Australia Post" and would remain a director until the meeting on November 30, 2012.
Mr Fleiter was appointed to the board in November last year (BD: Nov 15, 2011).
The company said that it had introduced a program to reduce overheads with savings on for personnel and consultants and a 50 percent reduction in remuneration for executive chairman Mr Pannuti.
Consegna said it had a lower that budgeted expenditure in the three months to September 30, 2102 but the additional savings would reduce expenditure a further 45 percent.
Consegna fell 0.1 cents or 14.3 percent to 0.6 cents with 2.5 million shares traded.

HEALTHLINX

Healthlinx annual general meeting passed all resolutions but there was 27.15 percent dissent against the election pf former managing director Nick Gatsios as a director.
Healthlinx said that 107,585,469 proxy votes (72.85%) supported the election of Mr Gatsios, with 40,093,878 proxy votes (27.15%) against.
The remuneration report was passed with 4,354,290 proxy votes (4.48%) opposed and 92,759,909 proxy votes (95.52%) in favor and a resolution to accept further payments under a La Jolla Cove convertible note was opposed by 12,828,889 proxy votes with 130,317,417 proxy votes in favor.
The company's most recent Appendix 3B said that Healthlinx had 651,270,379 shares on issue meaning that the largest number of opposition votes to the election of Mr Gatsios amounted to 6.16 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.
Healthlinx was unchanged at 0.2 cents.

NUSEP

Nusep says directors Iain Sorrell, David Roffe and Ward Wescott will retire from the conclusion of the annual general meeting on November 30, 2012.
Nusep said that the meeting resolution for the re-election of Mr Sorrell would be withdrawn and three resolutions for the extraordinary general meeting on the same day would also be withdrawn.
The company said it would announce additional board members shortly.
In its notice of meeting Nusep said it was prepared for a 'second strike' on its remuneration report, with an extraordinary general meeting to re-elect all six directors immediately after the annual general meeting (BD: Oct 31, 2012).
The extraordinary general meeting will now only consider the reelection of chairman John Manusu and Andrew Goodall.
Nusep was untraded at 6.7 cents.

GI DYNAMICS

GI Dynamics says 18,095,072 US shares, equivalent to 90,475,360 Australian CDIs will be released from voluntary escrow on November 30, 2012.
GI Dynamics most recent Appendix 3B said that the company had 286,787,655 shares outstanding and it is believed that all shares in voluntary and ASX escrow are part of that number.
GI Dynamics chief financial officer Robert Crane told Biotech Daily there were about 48 million shares in voluntary escrow which would be available for sale in March 2013 and about six million shares subject to the 24 month ASX imposed escrow from the IPO date, available from September 2013.
In its media release to the ASX, GI Dynamics said the company would also release 1,082,140 options, equivalent to 5,410,700 CDI options from voluntary escrow on November 30, 2012
GI Dynamics was up three cents or 4.8 percent to 65 cents.