Biotech Daily

Thursday January 30, 2014

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: BIONOMICS UP 6%, CLINUVEL DOWN 18%**

*** MESOBLAST: 'STEM CELLS EFFECTIVE FOR LOW BACK PAIN'**

*** CANADA APPROVES ATCOR'S SPHYGMOCOR XCEL**

*** VIRALYTCS $23m PLACEMENT, $4m RIGHTS ISSUE**

*** PATRYS SHORTFALL RAISES $925k, TOTAL $7.7m**

*** EU REGULATOR DELAYS CLINUVEL SCENESSE REVIEW TO MID-2014**

*** PROGEN PLEADS MEDIGEN PI-88 PROGRESS TO ASX 17% QUERY**

*** LANDON CLAY, EAST HILL TAKE 11% OF BIOTA**

*** MEDIGARD HAS ONE QUARTER CASH**

*** EYEON, SPACETIME, STEPHEN COPULOS TAKE 7% OF HEALTHLINX**

*** QUEENSLAND MM, BRYAN FROST TAKE 10% OF HEALTHLINX**

MARKET REPORT

The Australian stock market fell 0.78 percent on Thursday January 30, 2014 with the S&P ASX 200 down 40.9 points to 5,188.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and four were untraded.

Bionomics was the best, up four cents or 5.9 percent to 72 cents, with 1.4 million shares traded. Pharmaxis climbed four percent; Admedus, Alchemia, Atcor and Uscom were up more than three percent; Living Cell and Patrys rose more than two percent; Genetic Technologies, Prana, Resmed and Universal Biosensors were up more than one percent; with Psivida up 0.2 percent.

Clinuvel led the falls, down 27 cents or 18.4 percent to $1.20 with 20,937 shares traded. Impedimed lost 8.5 percent; Antisense fell 7.1 percent; Avita was down 6.9 percent; Anteo was down 5.3 percent; Circadian, Phosphagenics and Viralytics fell more than four percent; Cellmid, Oncosil, QRX and Tissue Therapies were down more than three percent; Acrux, Cochlear, Ellex, Nanosonics, Prima, Sirtex and Starpharma shed one percent or more; with CSL and Mesoblast down by less than one percent.

MESOBLAST

Mesoblast says a 100-patient, phase II trial shows its mesenchymal precursor cells reduce pain and improve function in patients with discogenic low back pain.

Mesoblast said the 12-month trial showed that a single injection of mesenchymal precursor cells into degenerating intervertebral discs reduced low back pain and improved function in patients with chronic, moderate-to-severe discogenic low back pain.

The company said that treated patients used fewer opioids for pain relief, had greater radiographically-defined disc stability and underwent fewer additional surgical and non-surgical treatment interventions and the stem cells appeared to be well tolerated.

Mesoblast chief executive Prof Silviu Itescu said the trial was primarily designed to assess the safety of the stem cells for intervertebral disc repair, but “we have seen strong indications of sustained efficacy across a broad number of clinical and radiographic parameters after a single intra-disc injection”.

“Mesoblast plans to meet shortly with regulatory authorities in major jurisdictions, including the United States Food and Drug Administration, to discuss product registration trials for the potential treatment of disc degeneration,” Prof Itescu said.

The trial’s clinical investigator and medical director of the Los Angeles, California-based Cedars-Sinai Spine Center Dr Hyun Bae said the results were “compelling evidence that Mesoblast's stem cell technology has the potential to change the treatment of spinal disease from focusing on surgical reconstruction to biologic regeneration”.

Mesoblast said the results supported pre-clinical data which showed that its stem cells increased proteoglycan content and improved disc structure in sheep (BD: Sep 10, 2009).

The company said that 30 patients received six million stem cells in hyaluronic acid, 30 received 18 million stem cells in hyaluronic acid, 20 received hyaluronic acid alone and 20 received saline, all via intra-disc injection.

Mesoblast said the patients would be evaluated for safety and efficacy over 36 months but at 12 months there was a statistically significant reduction in mean pain score with the 18 million cell dose group reduced by 40 points and a non-significant reduction for the six million cell group down 37 points compared to the two control groups both reducing by 27 points ($p= 0.046$; $p = 0.11$, respectively).

The company said that both stem cell treatment groups had significant differences in achieving a greater than 50 percent reduction in pain score, “a key target” for treatment.

Mesoblast said that the lower dose treatment group had a greater proportion of patients with minimal residual back pain at 12 months, but both treatment groups had statistically significant pain reductions compared to controls.

The company said that at 12 months, mean daily use of opioid medications for back pain was reduced by 42 percent in the 18 million cell group compared with the saline control group ($p = 0.17$) and mean opioid use was more than two-fold higher in saline and hyaluronic acid controls achieving greater than 50 percent reduction in pain score than in stem cell-treated patients, indicating that pain reduction in the controls might have been due to high opioid intake rather than to any biologic effect.

Mesoblast said that patients treated with stem cells had a reduced need for additional surgical and non-surgical interventions for pain and stem cell-treated patients had greater improvement in function than controls.

The company said that stem cell- treated patients achieved a non-statistically significant minimal residual functional disability at 12 months compared to controls.

Mesoblast said that stem cell-treated patients demonstrated a significant reduction in radiographically-determined translational movement of the disc, suggesting a treatment effect on disc degeneration, anatomy, and improved disc stability.

Mesoblast fell five cents or 0.85 percent to $5.80 with 540,020 shares traded.

ATCOR MEDICAL

Atcor says that Health Canada has approved its Sphygmocor XCel non-invasive measure of central aortic blood pressures and arterial stiffness.

Atcor said that Canada had 35 million people and hypertension or high blood pressure affected more than one in five Canadian adults.

The company said that 22.7 percent of the population over 20 years old in 2007 had been diagnosed with hypertension, with heart disease and stroke costing the Canadian economy more than $C20.9 billion ($A21.4 billion) every year in physician services, hospital costs, lost wages and decreased productivity.

Atcor chief executive officer Duncan Ross said the company was "successful selling direct in Canada where Sphygmocor is currently used in a number of leading hospitals".

"Sphygmocor XCel approval provides Atcor with an excellent opportunity to offer existing clients new technology and expand our share of the clinical market," Mr Ross said.

"The Canadian health care system is facing the same challenges as others around the world, particularly meeting the increasing costs of servicing the health demands of an aging population," Mr Ross said.

"We believe that tools such as Sphygmocor, which can identify risks early and help patients adopt preventative strategies, will be attractive to health authorities, specialists and clinicians," Mr Ross said.

"Our technology complements the Public Health Agency of Canada's 2013-2016 'Preventing Chronic Disease Strategic Plan', which guides the Agency's investments in healthy living and chronic disease prevention," Mr Ross said.

Atcor was up half a cent or 3.7 percent to 14 cents.

VIRALYTICS

Viralytics says it has raised $23 million in a placement and hopes to raise a further $4.1 million through a one-for-six non-renounceable rights issue at 28 cents a share.

Viralytics said that the record date for the rights issue was February 7, with the offer opening on February 11 and closing on February 25, 2014.

The company said the proceeds were expected to "fund the company to the end of 2016 including the completion of its key Cavatak clinical trials" including a phase II trial for late-stage melanoma, a phase II melanoma trial due to begin by the end of 2014 and a phase I/II trial for solid tumors due to begin in February 2014.

Viralytics said it had binding commitments for the two-tranche placement with the second tranche subject to shareholder approval.

The company said that Bell Potter Securities was the lead manager for the capital raising and Roth Capital Partners acted as sole US placement agent.

Viralytics chief executive officer Dr Malcolm McColl said the company achieved "major advances with Cavatak in 2013 with excellent momentum entering 2014".

"This capital raising is transformational for the company as it introduces several high quality international institutional investors to the register for the first time," Dr McColl said.

"We can now more rapidly advance the program and will be in a strong financial position to negotiate with pharmaceutical partners and optimize commercial outcomes," Dr McColl said.

"Support from leading specialist healthcare funds in the US and UK and small cap investors in Australia recognizes the increasingly promising clinical trial outcomes achieved by the company in 2013 and validates the outstanding commercial potential of Cavatak, our oncolytic immunotherapy technology," Dr McColl said.

Viralytics fell 1.5 cents or 4.7 percent to 30.5 cents.

PATRYS

Patrys says it has raised a further $925,000 the placement of 18,500,000 shares at five cents a share as part of the shortfall from its rights issue.
In December, Patrys raised $5.5 million in the rights issue with a further $1.3 million raised in earlier this month (BD: Dec 16, 2013; Jan 19, 2014).
Patrys was up 0.1 cents or 2.3 percent to 4.4 cents with 2.4 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency has extended the marketing authorization application review period for Scenesse to mid-2014.
Clinuvel said it filed the application for Scenesse (afamelanotide 16mg implant for the orphan light-intolerance disorder erythropoietic protoporphyria in adults in 2012.
Clinuvel acting chief scientific officer Dr Dennis Wright s said that the review of a “first-in-class drug albeit for an untested disease in which light exposure plays a dominant role, was always going to be subject of a lengthy regulatory review”.
Dr Wright said that the Agency had requested additional time to review data from the US phase III erythropoietic protoporphyria study which was submitted last year.
In 2013, Clinuvel said the study failed to meet its primary endpoint, but treated patients showed “a strong trend” for sunlight exposure compared to placebo (BD: Nov 11, 2013).
Dr Wright said the evaluation clock had been stopped until June 2014 and the company would work with the EMA to address any further questions.
Clinuvel chief executive officer Dr Philippe Wolgen said the company had “much confidence in the EMA’s approach to learn as much as possible about the clinical aspects of the disease and the clinical relevance of the treatment to patients”.
“This extended review period will also allow time for … patients and expert physicians to share their experience with the EMA,” Dr Wolgen said.
Clinuvel fell 27 cents or 18.4 percent to $1.20.

PROGEN PHARMACEUTICALS

Progen has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 16.7 percent from 39 cents on January 28 to 45.5 cents today, January 30, 2014 but did not note an increase in trading volume.
Progen said investors were increasingly aware of advances in the phase III trial of PI-88 for liver cancer by Taiwan’s licencee Medigen, which met the target enrolment of 500 patients at the end of 2013 (BD: Jan 19, 2014).
Progen was up 12 cents or 28.6 percent to 54 cents with 49,262 shares traded.

BIOTA PHARMACEUTICALS

The Providence, Rhode Island-based Landon T Clay and East Hill Holding Co have increased their holding in Biota from to 3,060,661 shares to 3,056,066 shares (10.8%).
Immediately prior to Biota’s 2012 merger with Nabi Pharmaceuticals and departure from the ASX to the Nasdaq, Landon Clay, East Hill Holding Co and associates increased their substantial shareholding to 24,485,284 shares (13.07%), equivalent to 3,060,661 post-merger shares (BD: Oct 30, 2012).
Last night on the Nasdaq, Biota was up 24 US cents or 5.13 percent to $US4.92 ($A5.63), equivalent to 70.4 cents pre-merger) with 81,167 shares traded.

MEDIGARD

Medigard says its net operating cash burn for the three months to December 31, 2013 was $65,000 with cash at the end of the quarter of $45,000 and a loan facility of $20,000.
Medigard did not provide further details.
Medigard was untraded at 2.7 cents.

HEALTHLINX

Eyeone No 2 Pty Ltd and former director Stephen Copulos have become a substantial shareholder in Healthlinx with 866,412,648 shares or 6.86 percent of the company.
The substantial shareholder notice said that shares were acquired as part of the deed of company arrangement annual general meeting (BD: Jan 21, 2014).
The notice said the holders of the shares were Eyeon and Spacetime Pty Ltd and was signed by Mr Copulos of Shepparton Victoria.
In 2007, Mr Copulos invested in Healthlinx and was described at the time as a “white knight” investor, becoming substantial through the Copulos Group in April 2007 and in 2008 holding 15,634,200 shares or 19.2 percent of Healthlinx (BD: May 26, 2008).
Mr Copulos was appointed as a director in June 2007 and resigned in December 2010 (BD: Jun 19, 2007; Jan 16, 2011).
When he resigned as a director, Mr Copulos told the ASX in an Appendix 3Z notice that he had an indirect interest in 33,838,761 shares (21.9%) through Supermax Pty Ltd, HSBC Custody Nominees for Citywest Corp as trustee for the Copulos (Sunshine) Unit Trust and Citywest Corp as trustee for the Copulos (Sunshine) Unit Trust.
Healthlinx subsequently entered into draw down equity facilities, first with the New York based Springtree and later with La Jolla Cove Investors.
Healthlinx was in a suspension.

HEALTHLINX

Queensland MM Pty Ltd says it has become a substantial shareholder in Healthlinx with 1,253,300,000 shares or 9.93 percent of the company.
The substantial shareholder notice said that shares were acquired as part of the deed of company arrangement annual general meeting (BD: Jan 21, 2014).
The notice was signed by Peregrine Corporate executive chairman Bryan Frost of Armadale, Victoria.