

Biotech Daily

Friday January 31, 2014

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH UP: CLINUVEL UP 18%, ANTEO DOWN 11%
- * CELLADON LISTS ON NASDAQ FOR MYDICAR HEART TREATMENT
- * ACRUX, ELI LILLY AXIRON SALES UP 142% TO \$203m, \$28m 'DIVIDEND'
- * HEALTHLINX ENDS ADMINISTRATION, TRENT TELFORD TAKES 10%
- * PROGEN RECEIVES \$974k FEDERAL R&D TAX REFUND
- * RHINOMED LAUNCHES TURBINE AT BIKE RACES, FACEBOOK
- * MEDIVAC HOPES FOR FUNDS, TO REBADGE AS WOOLWICH CAPITAL

MARKET REPORT

The Australian stock market edged up 0.04 percent on Friday January 31, 2014 with the S&P ASX 200 up 1.9 points to 5,190.0 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and four were untraded.

Clinuvel was the best, up 21.5 cents or 17.9 percent to \$1.415, with 81,990 shares traded.

Prana and Viralytics climbed more than eight percent; Atcor, Impedimed and Oncosil rose seven percent or more; Medical Developments, Prima and Reva were up more than four percent; Cellmid was up 3.2 percent; Alchemia and Benitec rose more than two percent; Living Cell, Mesoblast, Sirtex, Starpharma and Universal Biosensors were up more than one percent; with Osprey and Resmed up by less than one percent.

Anteo led the falls, down two cents or 11.1 percent to 16 cents with 13.3 million shares traded.

Optiscan lost 8.6 percent; Admedus, Antisense, Avita, Ellex, Genetic Technologies and Nanosonics fell more than three percent; QRX shed 2.4 percent; Acrux was down 1.3 percent; with Cochlear, CSL and Psivida down by less than one percent.

CELLADON

Celladon has listed on the Nasdaq to develop gene therapy for congestive heart failure, partly developed at Melbourne's Baker IDI Heart and Diabetes Institute.

GBS Venture Partners partner Dr Joshua Funder is a director of the San Diego, California-based Celladon and told Biotech Daily that GBS had followed the company for nine years, invested in it in 2012 and held about six percent of the company.

In a media release GBS said that it invested in Celladon in February 2012 as part of a \$US53 million private financing from a syndicate which included Pfizer Ventures, Novartis Venture Funds, Lundbeckfond Ventures, Tekla Capital and MPM Capital.

"Celladon is the third GBS portfolio company to successfully list on the Nasdaq since the beginning of 2013," Dr Funder said.

Celladon said it was conducting a 200-patient phase IIb study in Europe and the US, entitled 'Calcium Up-Regulation by Percutaneous Administration of Gene Therapy In Cardiac Disease' or Cupid.

The company said that the multinational, multi-center, double-blind, placebo-controlled, randomized study of its Mydicar genetically-targeted enzyme replacement therapy drug was recruiting subjects with results expected by July 2015.

Celladon said that Mydicar was targeting the sarco-endoplasmic reticulum calcium ion adenosine triphosphatase or SERCA enzyme.

Celladon said that heart failure was "one of the most expensive and debilitating conditions facing the US health care system [costing] about \$US39.2 billion in direct and indirect costs in 2010, primarily because patients are chronically in and out of intensive care units".

The company said that Mydicar was a one-time outpatient infusion in a cardiac catheterization laboratory, similar to undergoing an angiogram and was designed to restore levels of an enzyme known to play a key role in the progression of heart failure. Celladon said that repairing the molecular defect in preclinical studies reversed the disease and restored cardiac function and in a phase II clinical trial of 39 patients, the frequency of death, worsening heart failure, heart failure-related hospitalizations, heart transplant and need for a mechanical heart pump was dramatically lower and sustained for patients on high-dose Mydicar compared with placebo.

The company said that active treated patients' ability to exercise, symptoms of heart failure and quality of life improved.

Celladon said that Mydicar's molecular target was an enzyme found in the sarcoplasmic reticulum, critical to the contraction of the cardiac muscle cell, by coordinating the contraction and relaxation of calcium ions.

The company said that the heart muscle's ability to contract and to pump blood and maintain oxygenation of the body was determined by a continual re-loading of the sarcoplasmic reticulum with calcium ions to prepare for the next cycle of contraction. Celladon said that the key factor that enabled the re-loading of the sarco-endo-plasmic reticulum with calcium ions was the enzyme SERCA2a.

The company said that studies had established a clear association between depleted SERCA2a enzyme in cardiac cells and the progression of end-stage heart failure and Mydicar targeted the SERCA2a enzyme.

Celladon's chairman is Michael Narachi and the chief executive officer is Dr Krisztina Zsebo.

The company announced its initial public offer pricing of \$US8.00 (\$A9.10) a share with an offer of 5,500,000 shares.

Last night on the Nasdaq, Celladon (CLDN) closed up 18 US cents or 2.25 percent at \$8.18 with 1,759,571 shares traded.

ACRUX

Eli Lilly says that sales revenue of Acrux's Axiron for 2013 was up \$US104.8 million or 141.8 percent to \$US178.7 million (\$A203.4 million).

Acrux chief financial officer Tony Dipietro told Biotech Daily that Eli Lilly's \$US25 million (\$A28.4 million) milestone payment for exceeding \$US100 million in Axiron sales in 2013 was expected "in the first week of March" 2014.

In a media release, Acrux said that the milestone payment was "superfluous to working capital requirements [and] will be distributed to shareholders as dividends".

Eli Lilly said that sales in the three months to December 31, 2013 was \$US53.0 million in the US and \$US900,000 in other territories with the total \$US53.9 million a 32.8 percent rise on the previous month and a 125.5 percent increase over the previous corresponding period.

According to Eli Lilly, in 2012, total sales were \$US73.9 million with a general rise each quarter except for a fall in the three months to September 30, 2012 to \$US16.0 million from the June quarter of \$17.7 million.

Eli Lilly said that in 2013, quarterly sales similarly fell in the three months to September 30, 2013 to \$US40.6 million from \$US47.1 million.

"We remain confident about the net sales growth prospects for calendar 2014," Acrux said.

Acrux fell three cents or 1.3 percent to \$2.32 with 1.6 million shares traded.

HEALTHLINX

Healthlinx says that following shareholder approvals at its annual general meeting on January 21, 2014, the company is no longer in external administration.

Healthlinx said that the administrators Hall Chadwick's David Ross and Shanon Thomson had established the Healthlinx Creditor's Trust and thereby wholly effectuated the deed of company arrangement executed on September 2, 2013.

Hall Chadwick said in a separate announcement that the control of the company had reverted to its directors effective on January 29, 2014.

Healthlinx failed to commercialize its Ovplex test for ovarian cancer and last year went into administration (BD: May 7, 2013).

In October 2013, Healthlinx raised \$70,000 from four sophisticated investors to fund a notice of meeting and provide working capital, leading to the satisfaction of the deed of company arrangement and the election of directors Richard Revelins, Trent Telford and Michael Quinert (BD: Oct 4, Dec 10, 2013; Jan 21, 2014).

This week, companies related to former director Stephen Copulos, Peregrine Corporate chairman Bryan Frost, Gleneagles Securities, LSAF Holdings and Chifley Portfolios became substantial shareholders in the company (BD: Jan 28, 30, 2014).

Today, Mr Telford said that with Cope Street Pty Ltd of Lane Cove, Sydney, he became substantial in Healthlinx with 1,253,350,000 shares (9.93%).

Healthlinx was untraded at a post-500-to-one-consolidation 50 cents

PROGEN PHARMACEUTICALS

Progen says it has received \$613,503 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Progen said the rebate related to research and development expenditure for the year to June 30, 2013

Progen fell four cents or 7.4 percent to 50 cents.

RHINOMED (FORMERLY CONSEGNA)

Rhinomed says it launched its sport technology the Breatheassist Turbine nasal plugs at the Santos Tour Down Under bicycle race in Adelaide and through Facebook.

Rhinomed said it was an official partner of the Tour and had a strong presence at all stages of the Tour as well as a site exhibiting the Turbine.

Rhinomed chief marketing officer Jane Ballantyne said the company's objective at the Tour Down Under was to introduce the technology and brand to the cycling elite.

"We undertook a sampling campaign that saw all professional teams receive the Turbine," Ms Ballantyne said.

"Many professional riders started trialing the product during the Tour and so far the feedback is very positive," Ms Ballantyne said.

Ms Ballantyne said that the company would be involved in the Jayco Herald Sun Tour in Victoria from February 5 to 9, 2014.

Rhinomed said its Facebook campaign had reached the news feeds of 2.6 million people and had more than 205,000 people actively engage with it.

Rhinomed fell 0.8 cents or 14.8 percent to 4.6 cents with 2.0 million shares traded.

MEDIVAC

Medivac says it hopes to raise funds, finalize its 2013 annual report and seek shareholder approval to change its name to Woolwich Capital to better reflect its activities.

Medivac said the delay in completing the annual report was "predominantly as a result of delays in expected financial settlements from its wholly owned subsidiary Republica Capital".

The company said it was more confident that it would "see some material improvement in valuations of the Republica portfolio, most of which has been written down due to a lack of third party valuations and delays in transactions, the fact remains that turnover in venture capital investment can be slow and difficult to predict".

Medivac said it intended to raise up to \$250,000 for general working capital purposes through a placement to sophisticated investors and was considering a share purchase plan to raise up to \$500,000.

Medivac was commercializing the Metamizer technology which was "an environmentally friendly system providing sterile, safe waste and reducing waste to landfill by up to 90 percent" by sterilizing and shredding, as well as its Sunnywipes hard surface wipes and hand sanitizing gels.

In 2012, the company said it had a "heads of terms of agreement" with Republica Capital for a potential merger to vend-in income-producing assets (BD: Jun 22, 2012). Medivac was untraded at 0.3 cents.