Biotech Daily

Monday March 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDICAL DEV UP 7%, TISSUE THERA DOWN 37%**

*** EUROPEAN BUREAUCRACY ENTANGLES TISSUE THERAPIES, AGAIN**

*** REGENEUS EXPANDS TO QUEENSLAND**

*** THORNEY INCREASES, DILUTED TO 5.6% IN MESOBLAST**

*** INVESTORS MUTUAL TAKES PROFIT ON MAYNE PHARMA**

*** ARMADA, ASSOCIATES TAKE 5.2% OF ALCHEMIA**

*** BIOXYNE RELEASES 8m ESCROW SHARES**

*** IMPEDIMED LOSES PEGGY BROOKER, PROMOTES MORTEN VIGELAND**

*** ONDEK APPOINTS DR JENNY HARRY CHIEF EXECUTIVE OFFICER**

*** HEALTHLINX, LA JOLLA COVE PART COMPANY**

MARKET REPORT

The Australian stock market fell 2.05 percent on Monday March 18, 2013 with the S&P ASX 200 down 104.8 points to 5,015.4 points. Eight of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and five were untraded. All three Big Caps fell.

Medical Developments was the best, up 17 cents or 9.3 percent to $2.00, with 22,520 shares traded.

Viralytics climbed 8.8 percent; Phylogica was up four percent; Compumedics climbed 3.1 percent; Alchemia, Prana and QRX rose more than two percent; with GI Dynamics up 1.4 percent.

Tissue Therapies led the falls, falling as much as 13.5 cents or 55.1 percent to 11 cents before closing down nine cents or 36.7 percent to 15.5 cents with five million shares traded.

Reva lost 7.3 percent; Pharmaxis and Uscom fell five percent or more; Cellmid, Optiscan and Phosphagenics were down more than four percent; Allied Health, Avita, Clinuvel and Starpharma were down more than three percent; Atcor, CSL, Mesoblast, Nanosonics, Neuren, Sirtex and Universal Biosensors shed two percent or more; Acrux, Heartware and Resmed were down more than one percent; with Cochlear down 0.7 percent.

TISSUE THERAPIES

Tissue Therapies has encountered another European Union bureaucratic hurdle in the path of marketing approval for its Vitrogro wound treatment.

Tissue Therapies said the British Standards Institute had given advice to the European Commission Medical Devices Group which then voted that Vitrogro should be regulated as a medicine and not a device.

The company said that an email from the British Standards Institute (BSI) last week was the first indication it had of any further consideration of the classification of Vitrogro.

Last year, Tissue Therapies was notified by the BSI that the "final classification" of Vitrogro was as a device (BD: Oct 30, 2012).

Tissue Therapies said at that time that the European Medicines and Healthcare Products Regulatory Agency confirmed classification as a medical device class three, but under Rule 13 instead of Rule 8, as was previously agreed and as a result, the Agency decided that a European Medicines Agency 'desk audit' review of manufacturing and quality data was required, which would take up to 210 calendar days.

Today, Tissue Therapies said that the 2012 classification as a device followed an expert review by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Tissue Therapies chief executive officer told Biotech Daily that the company "was working with the MHRA to convince the European Medicines Agency that the EC Medical Devices Group didn't have enough information to make a decision".

The company said that until the BSI email last week, the BSI advice was that it was waiting only for a formal start date for the European Medicines Agency (EMA) committee review of manufacturing quality data as the last step needed for the granting of Conformité Européenne (CE) mark and the start of sales.

Tissue Therapies said the approval process excluded sponsor companies like Tissue Therapies from direct contact with the EMA and the company was "entirely dependent on BSI to make the submissions and to keep it informed".

Tissue Therapies said that following the BSI email, it had arranged an independent expert review of the BSI submission to the EMA and that review indicated "that the [BSI] submission to the EMA was poorly constructed and did not provide adequate information for the Medical Devices Group".

Tissue Therapies said the independent advice also said that the MHRA remained convinced that the correct classification of Vitrogro was as a device.

The company said that the EC Medical Devices Group vote was not a formal decision.

Tissue Therapies said that if the EMA formalizes the Medical Devices Group vote that Vitrogro should be regulated as a medicine, appeal options would be available.

The company said an appeal would not attract additional regulatory charges, it would be able to put the facts directly, and the BSI would not participate in the appeal process.

Tissue Therapies said that a successful appeal would mean the process would revert to the maximum 210-calendar day review of manufacturing quality data, followed by the granting of CE Mark, but if it was not successful, then a pivotal clinical trial would be necessary and the planned US Food and Drug Administration venous ulcer trial would be used to satisfy both EU and US requirements.

Tissue Therapies said that subject to funding of about $8 million, the trial could start late this year or early 2014, to be completed in one year by adding, already identified, US trial sites, allowing sales to start simultaneously in the EU and the US by the end of 2015.

The company said that as a result of the European uncertainty, it had withdrawn the rights issue, until the classification was clarified (BD: Feb 27, 2013).

Tissue Therapies fell as much as 13.5 cents or 55.1 percent to 11 cents before closing down nine cents or 36.7 percent to 15.5 cents with five million shares traded.

REGENEUS

Regeneus says it has established a cell processing laboratory in Queensland to allow doctors to treat patients with its Hiqcell stem cell therapy for musculoskeletal conditions.
The Sydney-based Regeneus said the laboratory at the John Flynn Private Hospital on the Gold Coast was the first outside New South Wales.
The company said the Hiqcell process harvested a small amount of a patient's own stem cells in their adipose, or fat, tissue and the separated and concentrated regenerative cells were re-injected in osteoarthritic-affected joints such as knees, hips and ankles of the patient.
Regeneus said that the stem cells, in conjunction with adipocytes, synergized to reduce inflammation and repair damaged tissue.
The company said that the Hiqcell treatment procedure was done under the supervision of the treating medical specialist.
John Flynn Private Hospital orthopaedic surgeon Dr David Liu said that the hospital saw "in-clinic autologous cell-based regenerative medicine as a significant innovative therapy platform for musculoskeletal and other inflammatory conditions".
Regeneus human health commercial development director Steve Barbera said that the Gold Coast laboratory was "an exciting step for Regeneus as we increase our footprint across Australia and have the ability to offer our cell therapy to patients outside of New South Wales".
"We have had large numbers of enquiries from Queensland with previously no capacity to service the demand," Mr Barbera said.
Regeneus is a public unlisted company.

MESOBLAST

Thorney Holdings has increased its holding in Mesoblast from 17,342,093 shares to 17,600,000 shares but has been diluted from 6.83 percent to 5.59 percent.
In its change of substantial shareholder notice Thorney said the shares were acquired by Thorney Investment Group Australia Pty Ltd, Tiga Pty Ltd, Thorney Holdings Pty Ltd and Jamahjo Pty Ltd between January 12, 2011 and March 14, 2013, with 277,389 shares acquired at $1.20 each on November 16, 2011; 277,389 shares at $3.44 a share on May 28, 2012; 277,390 shares at $3.78 a share on November 26, 2012 and 200,000 shares at $6.30 a share on March 14, 2013.
Thorney did not disclose the vale of 774,261 shares sold in that period of time.
Last week, Mesoblast raised $170 million though the placement of 26,970,979 shares at $6.30 a share.
Mesoblast fell 15 cents or 2.4 percent to $6.10 with 350,081 shares traded.

MAYNE PHARMA

Investors Mutual has reduced its substantial holding in Mayne Pharma from 30,008,818 shares (6.47%) to 28,700,000 shares (5.19%).
The Sydney-based Investors Mutual, which is 47.5 percent owned by Treasury Group, said it acquired 4,250,000 shares for $1,253,750 or 29.5 cents a share and sold 5,558,818 shares for $2,182,460 or 39.3 cents a share.
Mayne Pharma was up 1.5 cents or 3.3 percent to 46.5 cents with 3.7 million shares traded.

ALCHEMIA

Armada Trading and associated companies have become substantial shareholders in Alchemia with 16,515,849 shares or 5.2 percent.
The initial substantial shareholder notice said that the Sydney-based Armada was associated with Pinwillow Pty Ltd a superannuation fund controlled by Anthony Berg, Trina Investments Pty Ltd, a company controlled by Anthony Berg, and Karen Martin.
The notice said that 2,353,353 shares were acquired for $700,000 or 29.74 cents a share on March 14, 2013.
Last week, Alchemia said it had placed $10 million at 30 cents a share (BD: Mar 11, 2013).
Alchemia was up one cent or 2.7 percent to 38 cents.

BIOXYNE

Bioxyne says that 7,987,199 shares will be released from ASX escrow on March 27, 2013.
Bioxyne said that following the release of the shares, 14,989,686 shares would remain in escrow, to be releases on April 3, 2014, with a total of 163,059,587 shares on issue.
Bioxyne was unchanged at 1.7 cents.

IMPEDIMED

Impedimed says that chief financial officer and chief operating Peggy Brooker has resigned.
Impedimed chief executive officer Richard Carreon said that Ms Brooker had run the company's global financial administration and back office operating functions.
Impedimed said its US headquarters had completed its strategic realignment, including the departure of sales and marketing senior vice-president William Gearhart and the business development senior vice-president Jack Butler and two other professionals.
The company said that Morten Vigeland would be the global finance vice-president.
Mr Carreon said the realignment had "delivered significant value in terms of dramatically lowering our cost structure, while driving double-digit growth in our core lymphoedema business".
Impedimed was unchanged at nine cents.

ONDEK

Ondek has appointed Dr Jenny Harry as its chief executive officer.
Ondek said it was developing medical therapies using discoveries by Nobel laureate Prof Barry Marshall including the use of the stomach bacteria Helicobacter pylori for childhood asthma and allergies (BD: Jun 29, 2011).
Ondek chairman Peter Hammond said that Dr Harry was formerly the chief executive officer and managing director of Tyrian Diagnostics and had experience with high performing teams, strategic planning and portfolio development, structuring and negotiating agreements with multi-nationals, raising capital for early stage biotechnology companies and investor relations.
Ondek said that Dr Harry had a Doctorate of Philosophy in developmental biology from Macquarie University and was a graduate of the Harvard Business School general manager program.
The company said that Dr Harry was based at Sydney's Exto Partners.
Ondek is a private company.

HEALTHLINX

Healthlinx says it has completed negotiations to terminate its funding agreement with La Jolla Cove Investors.

Healthlinx said that the funding agreement was entered into in December 2011 to provide up to $9,000,000 over three years through a convertible debenture and a settlement had been executed without penalty.

The company said that the termination of the facility would allow the company to seek alternative funding for its operational activities and the ongoing commercialization of its Ovplex ovarian cancer diagnostic in Asia and Europe.

Healthlinx was untraded at 0.1 cents.