Biotech Daily

Tuesday March 15, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTHEA UP 8%, USCOM DOWN 6%**

*** GI DYNAMICS ENDOBARRIER FAILS SAFETY, EFFICACY**

*** CLINUVEL RAISES $8m, PREPARES EUROPEAN SCENESSE CENTRES**

*** MEDICAL DEVELOPMENTS, CSIRO COMPLETE NEW TECHNOLOGY**

*** CANADA APPROVES ADHERIUM'S SMARTTURBO, SMARTTOUCH**

*** INTERNATIONAL STEM CELL TO RAISE $8m**

*** VIRALYTICS CANON TRIAL: 'CAVATAK SAFE, ANTI-CANCER ACTIVITY'**

*** OBJ PLEADS SCHULTZ TO ASX 18% QUERY**

*** AVITA ENROLS RENOVACELL RE-PIGMENTATION STUDY**

*** LAGODA, FATIMA DICKEY, RICHARD BAYLES TAKE 10% OF CLINUVEL**

*** DEUTSCHE BANK 'RETURNS' BELOW 5% OF GENETIC TECHNOLOGIES**

*** HEARTWARE APPOINTS CHADWICK CORNELL DIRECTOR**

*** UNILIFE CHAIR ALAN SHORTALL GOES WITH $2m, RAMIN MOJDEH GOES**

MARKET REPORT

The Australian stock market fell 1.43 percent on Tuesday March 15, 2016 with the ASX200 down 74.1 points to 5,111.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Opthea was the best, up three cents or 7.7 percent to 42 cents with 121,030 shares traded. Clinuvel climbed 5.45 percent; Neuren was up 4.35 percent; Osprey and Pro Medicus were up more than three percent; Starpharma and Tissue Therapies rose more than two percent; Biotron, Ellex, Orthocell and Polynovo were up more than one percent; with Nanosonics and Viralytics up by less than one percent.

Uscom led the falls, down one cent or 6.1 percent to 15.5 cents with 108,207 shares traded. Avita fell 4.55 percent; Actinogen, Admedus, IDT, Impedimed and Oncosil were down more than three percent; Acrux, Antisense, Living Cell, Medical Developments, Pharmaxis and Prima shed two percent or more; Anteo, Bionomics, Cochlear, CSL, Mesoblast and Prana were down more than one percent; with Resmed and Sirtex down by less than one percent.

GI DYNAMICS

GI Dynamics says that its pivotal Endobarrier trial for obesity and type 2 diabetes failed to meet its primary safety and efficacy endpoints.

GI Dynamics said that last year it terminated the planned 500-patient 'Endo' trial with 325 patients enrolled following seven cases of the bacterial liver infection hepatic abscess (BD: Jul 30, 31, 2015).

Today the company said that the smaller final sample size provided "less statistical power for analyses than originally planned … [but] the pre-specified analysis methods were used to obtain the results … based on final data locked at March 3, 2016.

GI Dynamics said that the trial showed efficacy for the treatment of type 2 diabetes with an average reduction of haemoglobin A1c (HbA1c) from baseline to 12 months of 0.71 percent greater with the device than with sham intervention.

The company said that the effectiveness did not meet the protocol-specified primary efficacy endpoint, a statistical test to demonstrate a greater than 96.5 percent probability that the change in HbA1c was at least 0.4 percent greater with Endobarrier than with sham control.

GI Dynamics said that the pre-specified probability criterion was 96.5 percent, compared with the result of 92.8 percent.

The company said that the results were encouraging, "given that the trial only enrolled two-thirds of the intended subjects and because of early suspension of the trial, data for nearly one-third of the enrolled and randomized subjects were not available for the protocol-specified primary efficacy analysis".

GI Dynamics said that the Endobarrier did not meet the protocol-specified primary safety endpoint, defined by device-related serious adverse events requiring early device removal.

The company said that device-related serious adverse events requiring removal occurred in 11.7 percent of subjects, not meeting the protocol-specified primary safety endpoint criterion, a statistical test to demonstrate the incidence of primary safety events with Endobarrier was less than 15 percent.

GI Dynamics said that the pre-specified probability criterion was 96.5 percent, compared with the result of 90.5 percent.

The company said that the safety failure was largely due to the excess number of hepatic abscess that occurred in subjects implanted with the device.

GI Dynamics said that no additional cases of hepatic abscess were identified or reported since the trial was terminated in July 2015.

The company said that all subjects with previous hepatic abscess had complete resolution with no known clinical subsequent disease reported.

GI Dynamics said that it planned to submit the final trial report to the US Food and Drug Administration in April 2016 and expects peer-reviewed publications and presentations at scientific conferences to provide the public with a more detailed analysis of the trial data.

The company said that although the trial did not achieve its primary safety endpoint, evaluation of the safety data showed an opportunity to improve the clinical algorithm for the use of Endobarrier therapy.

GI Dynamics said that based on the clinically-relevant efficacy demonstrated in the Endo trial, it planned to continue discussions with the FDA for the purpose of seeking approval of an investigational device exemption to conduct a new US clinical trial to determine the efficacy and safety of Endobarrier using the revised clinical treatment algorithm.

The announcement was made after the market closed and GI Dynamics was untraded at two cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has raised $8.3 million through a placement at $3.30 a share to existing and new international institutional and professional investors.

Clinuvel said that the funds would enable it to pursue European commercialization of Scenesse (afamelanotide 16mg) for patients with erythropoietic protoporphyria (EPP).

Clinuvel chair Stan McLiesh said that “over many years our investors have been very patient to see through Clinuvel’s single focus on making Scenesse available to the EPP community”.

“We are in the last stages of preparing the commercial rollout of Scenesse and in navigating the final pan-European and country-specific requirements to make the product available in expert centres of care,” Mr McLiesh said.

Separately, Clinuvel said it was conducting site training and accreditation at the first of the European expert porphyria centres this week and, following training, the centres would be accredited to prescribe Scenesse to adult patients with erythropoietic protoporphyria.

Clinuvel climbed 18 cents or 5.45 percent to $3.48.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that with the Commonwealth Scientific and Industrial Research Organisation it has completed its new manufacturing technology.

Medical Developments chief executive officer John Sharman told Biotech Daily that the improvements were for the production of the methoxyflurane inhaled analgesic as well as the assembly and distribution of the “green whistle” inhaling device.

Mr Sharman said that the upgrade would include “state of the art” research and development laboratories for both pharmaceuticals and medical devices.

Medical Developments chairman David Williams told Biotech Daily that the new process would “significantly bring down the manufacturing cost … [as well as] improve our volume and stock management to underline our international push”.

In a media release Mr Sharman said the new technology would “help change the face of our company”.

“It provides us with significant production capacity improvements in terms of our ability to supply Penthrox, as well as delivering significant cost savings,” Mr Sharman said.

“We are building a new production facility which will incorporate our new manufacturing technology,” Mr Sharman said. “We have finalized the design of our facility and we expect construction to commence in the coming months.”

Mr Sharman said the new process and facility would need to be registered with the Australian Therapeutic Goods Administration which was expected “during 2016”.

Medical Developments fell 10 cents or 2.1 percent to $4.65.

ADHERIUM

Adherium says it has received Canadian approval to market its Smartturbo and Smarttouch devices for medication compliance.

Adherium said that the Smartturbo worked with Astrazeneca’s Symbicort Turbuhaler, and the Smarttouch device with a range of pressurised metred dose inhalers supplied by pharmaceutical companies, including Glaxosmithkline and Chiesi.

Adherium chief executive officer Garth Sutherland said the clearance “allows us to add Canada to the international markets which we already supply, including the US, Europe, China, Australia and New Zealand”.

Adherium fell one cent or two percent to 48 cents.

INTERNATIONAL STEM CELL CORPORATION

International Stem Cell says it has agreements with two institutional healthcare investors and management to raise $US6.3 million ($A8.4 million).
International Stem Cell said the placement included convertible preferred stock and warrants to purchase up to an additional $US25.7 million of common stock, to fund its phase I study of ISC-hpNSC for Parkinson's disease (BD: Mar 8, 2016).
The company said that the $US6.3 million comprised a purchase of $US2.5 million in cash for shares and the conversion of $3.8 million debt.
International Stem Cell said that co-chairman and chief executive officer Dr Andrey Semechkin purchased $US4.3 million of the preferred stock on the same terms as the outside investor through conversion of the $US3.8 million of indebtedness owed to him and $US500,000 in cash.
The company said that offer was expected to close about March 15, 2016.
International Stem Cell fell four US cents or 1.15 percent to $US3.45 with 8.1 million shares traded on the US over-the-counter market.

VIRALYTICS

Viralytics says that Cavatak has been shown to be safe, well tolerated and with anti-cancer activity for non-muscle invasive bladder cancer.
Viralytics said that data was presented on 14 patients in its Cavatak (Coxsackievirus A21) for non-muscle invasive bladder cancer (Canon) phase I trial of about 25 patients.
The company said that nine patients were treated by intra-vesicular administration of Cavatak as a monotherapy in the first stage of the trial and in the second stage, to date, five patients received a sub-therapeutic dose of the chemotherapy, mitomycin C, with Cavatak intra-vesically prior to routine surgical removal of the tumor tissue.
The company said that the study generated evidence of Cavatak targeting tumor cells with viral, that is Cavatak, replication and tumor cell death following either single or multiple administrations of Cavatak.
Viralytics said that anti-cancer activity including viral-induced tumor inflammation demonstrated in both the monotherapy and combination therapy arms of the study.
The company said that a complete response was observed in one of the three patients in the highest dose cohort of the monotherapy.
Viralytics said that to date the intra-vesicular administration of Cavatak had been generally well tolerated with no grade 2, 3 or 4 product-related adverse events.
The company said that the data was presented at the European Association of Urology congress in Munich, Germany, by the principal investigator, the University of Surrey’s Prof Hardev Pandha.
“The observed tumor targeting and viral replication seen in this study is likely to provide a strong signal in generating a local and systemic anti-tumour immune response,” Prof Pandha said.
Viralytics was up half a cent or 0.7 percent to 69 cents.

OBJ

OBJ 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 17.9 percent from 8.4 cents on March 11 to 9.9 cents on March 14, 2016 and noted an increase in trading volume.
OBJ fell 0.7 cents or 7.1 percent to 9.2 cents with 6.25 million shares traded.

AVITA MEDICAL

Avita says it has completed enrolment in its 10-patient study to evaluate the optimal use of Renovacell in patients with pigmentation defects.
Avita said there were a variety of ways to prepare skin with pigmentation issues, such as vitiligo and piebaldism, to efficiently receive its skin suspension generated by its Renovacell device.
The company said that researchers at the Netherlands Institute for Pigment Disorders were exploring the effectiveness of three approaches: superficial full surface ablation; fractional laser treatment; and conventional full surface carbon dioxide laser ablation.
Avita said the researchers would look at the percentage of re-pigmentation on recipient sites six months after treatment, as well as patient and physician reported outcomes.
Avita fell half a cent or 4.55 percent to 10.5 cents with 2.6 million shares traded.

CLINUVEL

Lagoda Investment Manager, Fatima Dickey and Richard Bayles have increased their holding in Clinuvel from 3,578,975 shares (8.04%) to 4,625,668 shares (9.83%).
The substantial shareholder noticed said that the shareholders included “various clients of Lagoda”, Merrill Edge, Oppenheimer, Fiduciary Trust, US Trust, JP Morgan, State Street, Brown Brothers, Northern Trust, Bank of New York Mellon, Wells Fargo and Fidelity.
The Columbus Circle, New York-based Lagoda said it acquired shares on-market between January 22 and March 11, 2016 at prices ranging from $2.80 to $3.61.

GENETIC TECHNOLOGIES

Deutsche Bank AG and associated entities say they have ceased their substantial holding in Genetic Technologies.
Last week, the London UK, Wilmington, North Carolina and Hong Kong based Deutsche Bank Securities reduced from 107,477,250 shares (6.27%) to 90,141,900 shares (5.26%) (BD: March 10, 2016).
Deutsche Bank said that between March 8 and 10, 2016 it borrowed and returned shares to below the five percent substantial level with no payments for the shares disclosed.
Genetic Technologies was unchanged at 1.9 cents.

HEARTWARE INTERNATIONAL

Heartware said that it has appointed Chadwick Cornell as an independent director expanding the board to 10 directors.
Heartware said that Mr Cornell was jointly selected with Engaged Capital as part of a cooperation agreement between the two companies (BD: Jan 29, 2016).
The company said that Mr Cornell was a managing director at private equity firm Goldner Hawn Johnson & Morrison, which he joined in 2013 following his tenure as Medtronic head of corporate development.
Heartware said that prior to Medtronic, Mr Cornell was a corporate lawyer at the Chicago, Illinois-based Sidley Austin, working on mergers and acquisitions and securities offerings.
The company said that Mr Cornell held a Bachelor's degree in accounting from Marquette University and a Juris Doctorate from the University of Pennsylvania Law School.
Last night on the Nasdaq Heartware fell four US cents or 0.13 percent to $US31.06 ($A41.45, equivalent to $1.18 before departing the ASX) with 248,216 shares traded.

UNILIFE CORP

Unilife says executive chairman Alan Shortall will receive $US1,486,802 ($A1,980,584) in termination pay and with chief operating officer Dr Ramin Mojdeh has resigned.

Unilife said that it had agreed to pay Mr Shortall $US420,000 for 12 months severance pay, $US420,000 for amounts otherwise owed under the employment agreement, $US420,000 for any bonus to which Mr Shortall might have been entitled, $US56,538 for unused vacation time, $US20,264 as reimbursement for relocation expenses, $US130,000 as reimbursement for relocation expenses for Mr Shortall and his family for repatriation to Australia and $US20,000 for legal fees.

The company said that the cash payments, other than the $US20,264, would not be paid to Mr Shortall as they would be offset in full by withholding obligations from the vesting of 4,000,000 restricted shares, that is, the tax owed by Mr Shortall on those shares.

Last night on the Nasdaq, Unilife US shares were up 5.7 US cents or 6.5 percent to 93.5 US cents ($A1.25).

Unilife said that Mr Shortall agreed to assign all inventions and works created by him during his employment with the company, to the extent that any such inventions and works were not previously assigned to the company.

Unilife said that Mr Shortall would “remain available as a consultant” and executive search firm Heidrick & Struggles would manage the search for a permanent chief executive officer.

The company said that senior vice-president, general counsel and secretary John Ryan had been appointed interim chief executive officer, with vice-chair Mary Kate Wold appointed as chair.

Unilife said that Ms Wold was the chief executive officer of the Church Pension Group, and was a former finance executive at Wyeth.

The company said that executive leadership team included chief financial officer David Hastings, the head of its wearable injector and auto injector business unit Ian Hanson and chief commercial officer Michael Ratigan.

The company said that it had streamlined its operations into two program-focused business units of prefilled syringes and wearable and auto injectors.

Unilife was unchanged at 19.5 cents with 1.1 million shares traded.