# Biotech Daily

Monday October 5, 2015

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH EVEN: AVITA UP 7%; BIOTRON DOWN 17%**

*** INVION CLAIMS INV102 SUCCESS FOR SMOKING CESSATION**

*** FDA DOUBLES AVITA RECELL COMPASSIONATE USE IDE**

*** CLINUVEL, FDA TALK SCENESSE FOR EPP**

*** ASCEND TREATS FIRST ASN-002 BCC PATIENT**

*** UNILIFE AGM FOR $99m SHARES**

*** PRESCIENT AGM FOR 700k DIRECTOR OPTIONS, 25m SHARES**

*** RON DEWHURST, KROY WEN TAKE 8% OF RHINOMED**

*** GOLDMAN SACHS BELOW 5% OF NANOSONICS, YET AGAIN**

## MARKET REPORT

The Australian stock market climbed 1.95 percent on Monday October 5, 2015, with the ASX200 up 98.5 points to 5,150.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and three were untraded. All three Big Caps were up.

Avita was the best, up 0.6 cents or 7.1 percent to nine cents with 1.5 million shares traded.

Nanosonics climbed 5.4 percent; Atcor was up 4.2 percent; Mesoblast, Prana, Sirtex, Uscom and Viralytics were up more than three percent; Cochlear, IDT and Universal Biosensors rose more than two percent; Acrux, Admedus, Compumedics, CSL, Impedimed and Medical Developments were up more than one percent; with Orthocell and Resmed up by less than one percent.

Biotron led the falls for the second trading day in a row, down 0.9 cents or 16.7 percent to 4.5 cents with 2.5 million shares traded, followed by Genetic Technologies down 13.0 percent to two cents with 1.1 million shares traded.

Living Cell lost 10 percent; Actinogen was down 8.9 percent; Antisense and Reva were down more than seven percent; Oncosil fell 5.7 percent; Anteo, Benitec, Pharmaxis and Tissue Therapies fell more than four percent; Optiscan shed 2.3 percent; Prima and Starpharma were down more than one percent; with Ellex and Pro Medicus down by less than one percent.

INVION

Invion says its 155-patient, phase II trial of INV102 (nadolol) for smoking cessation shows that it assists abstinence and reduces the number of cigarettes smoked.

Invion chief executive officer Dr Greg Collier told Biotech Daily the trial showed that INV102 was about twice as effective in patients remaining abstinent after eight weeks treatment at the maximum dose, compared to those on placebo.

The company reported that 12 of 62 patients (19.3%) treated with INV102 were abstinent at the end of dosing compared to seven of 59 patients (11%) administered the placebo.

Dr Collier compared the abstinence rates to "billion dollar" drugs including Pfizer's Chantix (varenicline) and Glaxosmithkline's anti-depressant Wellbutrin (bupropion), which had serious side effects but achieved similar differences from placebo in their phase III trials.

Dr Collier said there was a similar difference between the active and placembo groups in reducing by more than 70 percent the number of cigarettes smoked with 38 of the 62 patients on INV102 reducing their use by more than 70 percent compared to 21 of the 59 patients on placebo.

Dr Collier said that the reduction of the MUC5AC biomarker in collected sputum samples was also important.

In a media release, Invion said that INV102 reduced both MUC5AC and ERK1 in collected samples, supporting the hypothesis that INV102 had a novel mechanism of action directly targeting epithelial cells lining the airway.

The company said the data was "strong confirmation of the development strategy for both oral and inhaled INV102 for the treatment of airway disease".

Invion said that MUC5AC levels were reduced by 82 percent in INV102 treated patients, compared to 54 percent in placebo subjects, while ERK1 levels were reduced by 47 percent for INV102 compared with 27 percent for placebo.

Invion said that INV102 was safe and well tolerated and its titration scheme enabled patients to reach efficacious doses.

Dr Collier said that the company was looking forward to an end-of-phase II meeting with the US Food and Drug Administration and expected to file the application in November for a meeting early in 2016.

Invion said the data prepared INV102 to be developed as an inhaled treatment for chronic airway diseases including asthma, chronic obstructive pulmonary disease and cystic fibrosis and further data analysis would examine which patients responded to INV102 therapy and if this correlated with any of the several biomarkers measured in the sputum samples collected, with the aim of determining if it could generate further intellectual property around predicting patient response to INV102 and determining the best patient groups to be selected for phase III trials.

Invion said that all patients had tried to quit smoking multiple times but were defeated by chronic "smoker's cough" resulting from the build-up of mucus in their lungs following the last cigarette and the trial was designed to evaluate the efficacy of INV102 in improving rates of smoking cessation over a 10 to 12 week treatment period.

Invion chief medical officer Dr Mitchell Glass said the underlying pathology common to all respiratory diseases was the change in the airway epithelium lining the lung.

"These positive phase II data validate our approach for directly treating the airway epithelium even in the face of on-going insult, such as cigarette smoking," Dr Glass said.

"This is the first indication that epithelial damage can be treated directly by a drug," Dr Glass said. "There are currently no approved drugs capable of treating the change in the airway epithelium and these results pave the way for a potentially novel and better way of treating chronic airway diseases," Dr Glass said.

Invion was up 0.1 cents or 7.7 percent to 1.4 cents with 27.5 million shares traded.

## AVITA MEDICAL

Avita says the US Food and Drug Administration has expanded the Recell wound treatment compassionate use investigational device exemption program.

Avita said the program supplement allowed it to continue clinical evaluation of Recell on twice as many patients as originally permitted, allowing for treatment of 24 patients with insufficient healthy skin available for standard skin grafting of their injury.

The company said that investigational use of Recell in the patients might be granted in cases where the treating physician believed that there was no suitable treatment alternative.

Avita said the investigational device exemption allowed the use of Recell beyond burns and to larger, more serious defects than those previously studied in the US.

Avita chief executive officer Adam Kelliher said that the FDA doubling the number of compassionate use cases was “a significant achievement for Avita as we continue our pivotal US trial of Recell in burns [and] it provides an alternative treatment option for patients with no other skin-healing option”.

“The ability to achieve definitive closure of extensive injuries in this patient population can have a life-saving impact,” Mr Kelliher said.

Avita said the original 12-patient compassionate use exemption was approved in April 2014 and the procedures were “conducted with success at several leading institutions, including Wake Forest Baptist Medical Center, Maricopa Medical Center, Walter Reed National Military Medical Center and Medstar Washington Hospital Center”.

The company said that individual case results had been presented to the medical community at professional meetings in 2014 and 2015.

Avita said that last month, long-term results from two early compassionate use cases were presented at the Tissue Engineering and Regenerative Medicine International Society World Congress in Boston, Massachusetts, with surgeons from the Walter Reed National Military Medical Center presenting two complex trauma cases approved for compassionate use of Recell, and compared results to two similar cases not using Recell.

The company said the cases involved massive reconstruction using dermal regenerative templates and the patients had little available healthy skin to graft their defects closed, with the findings indicating that Recell allowed for a greater skin graft expansion, limiting donor site morbidity and decreasing donor site burden by 65 percent and showed a decreased time to complete healing of 50 percent relative to skin grafting without Recell and achieved outcomes with matching pigmentation.

Avita was up 0.6 cents or 7.1 percent to nine cents with 1.5 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it met with the US Food and Drug Administration last week to discuss the US regulatory review of Scenesse for US erythropoietic protoporphyria patients.

Clinuvel said the September 30, 2015 meeting was with the FDA’s Division for Dermatology and Dental Products and representatives of the Center of Drug Evaluation and Research and the Division “was seeking a regulatory pathway to make Scenesse available in the US, and the regulatory avenue of accelerated approval was suggested, pending FDA’s review, analyses and further discussions on available photo-provocation and data on quality of life in EPP patients”.

Clinuvel said that in 2014 Scenesse (afamelanotide 16mg) was granted marketing authorization by the European Medicines Agency as a prophylactic photo-protective drug for adult erythropoietic protoporphyria patients (BD: Oct 27, Jan 18, 2015).

Clinuvel was unchanged at $2.90.

## ASCEND BIOPHARMACEUTICALS

Ascend says its first nodular basal cell carcinoma patient in its 36-patient, phase I/IIa study of its injectable immunotherapy ASN-002.

The Melbourne-based Ascend said that basal cell carcinoma was a non-melanoma skin cancer diagnosed in an estimated two million people worldwide every year and was the most prevalent form of cancer in Australia, the US and Europe.

The company said that surgery was the primary treatment for basal cell carcinoma, but for many patients it could be a poor treatment option for both clinical and cosmetic reasons.

Ascend said that ASN-002 was a biologic therapeutic based on an adenovirus, a type of cold-virus, engineered to produce the immune-stimulatory anti-cancer protein interferon-gamma.

The company said that it had an exclusive licence to develop ASN-002, formerly known as TG1042, from France's Transgene SA.

Ascend said that three clinical studies had been completed in 64 patients with cutaneous lymphomas and advanced melanomas, demonstrating that ASN-002 was safe, well tolerated and conferred favourable clinical outcomes.

Ascend chief executive officer Dr Clement Leong said that ASN-002 had been "de-risked by the previous clinical studies and there is a strong biological rationale for its use in the treatment of [basal cell carcinoma]".

"We also believe there is a strong scientific rationale for the use of ASN-002 in a number of other cancers with important unmet medical needs, such as cutaneous lymphomas, bladder cancer and ovarian cancer," Dr Leong said.

Ascend said that the study would treat three cohorts of six patients each, with the dose and schedule for the remaining 18 patients in the expansion cohort to be based on the interim results.

The company said that the primary objective of the study was to evaluate the safety of ASN-002, with secondary objectives of evaluating the histological clearance and clinical responses of the nodular basal cell carcinoma over time.

Ascend said that interim results were expected by July 2016 and the study was expected to be completed by the end of 2016.

Ascend is a public unlisted company.

## UNILIFE

Unilife will vote to issue $US70 million ($A99.1 million) in shares increase directors fees to $399,000 and issue director Harry Hamill 35,000 shares.

Unilife said it proposed to issue $US45 million ($A63.7 million) in shares equivalent to 270,000,000 Chess depository instruments (CDIs) to Lincoln Park Capital Fund along with a further $US25,000,000 in shares to Cantor Fitzgerald & Co.

The company said that it sought approval to increase the total number of US shares on offer from 250,000,000 shares to 350,000,000 shares.

Unilife said that shareholders would be asked to approve the election of directors including chief executive officer Alan Shortall, Mary Katherine Wold, John Lund, William Galle, Jeff Carter and Harry Hamill.

The meeting will be held at the Rittenhouse Hotel, 210 West Rittenhouse Square, Philadelphia, Pennsylvania, on November 17, 2015 at 4pm (US EST).

Unilife was unchanged at 23 cents.

## PRESCIENT THERAPEUTICS

Prescient will vote to grant 700,000 options to directors Steven Engle, Steven Yatomi-Clarke and Dr James Campbell and approve the issue of 25,000,000 shares.
Prescient said that it proposed to issue the director options in three tranches, exercisable at 8.5 cents each with three years of issue.
The company said that the 25,000,000 shares were "for opportunities as they arise and to fund the company's operations".
Prescient said the annual general meeting would also vote to approve the 10 percent place facility and elect directors Mr Engle, Mr Yatomi-Clarke, Dr Cambell and Mr Hopper.
The meeting will be held at Chartered Accountants Australia & New Zealand, Level 3, 600 Bourke Street, Melbourne on November 4, 2015 at 11am (AEDT).
Prescient was untraded at seven cents.

## RHINOMED

Kroy Wen Pty Ltd says it has increased its substantial shareholding in Rhinomed from 37,890,355 shares (7.02%) to 50,000,000 shares (8.14%).
The notice was signed by Kroy Wen director and former Legg Mason funds manager Ronald Dewhurst, of South Yarra, Victoria.
Kroy Wen ("New York" backwards) and Mr Dewhurst became substantial in Rhinomed last year (BD: Sep 9, 2014).
Kroy Wen said that 734,645 shares were bought on January 29 and September 18, 2015 for $24,068 or 3.28 cents a share and a further 11,375,000 shares were acquired in Rhinomed's $2.5 million capital raising on September 24, 2015 at 3.2 cents a share (BD: Sep 18, 2015).
Rhinomed fell 0.1 cents or 3.1 percent to 3.1 cents.

## NANOSONICS

The Delaware-based Goldman Sachs Group says it has ceased its substantial shareholding in Nanosonics, again.
After the market closed on October 1, Goldman Sachs said it had become a substantial shareholder in Nanosonics with 14,256,636 shares or 5.03 percent, buying or borrowing shares, with the single largest acquisition on September 8, 2015 of 79,008 shares for $101,920 or $1.29 a share, while the single largest transaction was on September 29, 2015 of 1,247,750 shares for no applicable consideration (BD: Oct 2, 2015).
After the market closed on October 2, Goldman Sachs said it had bought 62,098 shares for $81,100 or an average price of $1.306 a share, but 1,247,750 shares were the subject of a "return of shares to the counterparty under a repurchase agreement" for no applicable consideration.
Previously, under a counterparty agreement, Goldman Sachs returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australian, HSBC Custody Nominees Australia and the Bank of New York Mellon (BD: Apr 13, 2015).
Nanosonics was up seven cents or 5.4 percent to $1.37.