Biotech Daily

Monday October 28, 2013

Daily news on ASX-listed biotechnology companies

VALE LOU REED 1942-2013

*** ASX, BIOTECH UP: CELLMID UP 22%, BIONOMICS DOWN 10%**

*** AUSBIOTECH INVESTOR CONFERENCE; CEO DR ANNA LAVELLE BACK**

*** CLINUVEL SCENESSE EFFICACY IN TWO HAILEY-HAILEY PATIENTS**

*** INVION PAYS ACCOLADE $500k FOR ZAFIRLUKAST FOR ASTHMA**

*** ALLIED PLEADS SCHULTZ TO ASX 60% QUERY**

*** MESOBLAST PARTNER JCR FILES FOR FIRST JAPAN MSC APPROVAL**

*** ATCOR $625k GERMAN TRIAL CONTRACT**

*** PROF RUTH BISHOP WINS $50k AIPS, CSL FLOREY MEDAL**

MARKET REPORT

The Australian stock market was up 1.02 percent on Monday October 28, 2013 with the S&P ASX 200 up 55.1 points to 5,441.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and three were untraded.

Cellmid was the best, up 0.8 cents or 21.6 percent to 4.5 cents with 25.0 million shares traded.

Atcor and Phosphagenics climbed more than six percent; Benitec was up 5.4 percent; Anteo and Avita were up more than four percent; Allied Health, CSL and IDT were up three percent or more; Genetic Technologies, Prana and Prima rose more than two percent; Mesoblast was up 1.4 percent; with Clinuvel, Reva and Sirtex up by less than one percent.

Bionomics led the falls, down 7.5 cents or 9.8 percent to 69 cents with 1.6 million shares traded.

Optiscan and Nanosonics lost five percent or more; Medical Developments fell 3.5 percent; Alchemia, Impedimed, Starpharma, Universal Biosensors and Viralytics shed more than two percent; Acrux, Ellex, Living Cell, QRX and Resmed were down more than one percent; with Cochlear down 0.3 percent.

LOU REED

It might seem highly unusual for Biotech Daily to mark the death last night of New York musician and songwriter Lou Reed from liver failure, but he was an inspiration to many, and in many different ways.

Lou was my first interview, nearly 40 years ago, so if some people think I'm a tough 'newspaper Joe' you could blame Lou for some of that. Unlike many reporters, my interview with Lou went well and it is quite possible that if it was otherwise, I might not have continued in the calling of journalism.

His 'Magic and Loss' album about the death of two friends from late-stage HIV and cancer addresses the interventions we hope may save or extend life, with the inevitable result.

There have been countless times that the editing of Biotech Daily has been fueled by the adrenaline-pump of Lou Reed and the Velvet Underground.

Thank you, Lou.

David Langsam
Editor

AUSBIOTECH

Ausbiotech chief operating officer Glenn Cross says that chief executive officer Dr Anna Lavelle has returned from sick leave and will attend the Brisbane conference this week.

Mr Cross told Biotech Daily that Dr Lavelle had returned to work part-time and would be at the main conference in Brisbane.

In his official welcome to the two-day Melbourne 'Biotech Invest 2013' Conference Mr Cross said that 350 delegates were attending the meeting at the Melbourne Convention and Exhibition Centre.

Mr Cross told Biotech Daily that the biotechnology meeting preceding a mining investment conference later this week and conference partner Beacon Events had arranged for the latter group to attend the Biotech Invest.

Mr Cross said that the major Brisbane conference had been locked-in four years ago.

Victoria's Minister for Technology Gordon Rich-Phillips used his welcoming address to delegates to announce the launch of a 'Guide for Life Science Company Directors' developed by Ausbiotech and approved by the Australian Institute of Company Directors".

Mr Rich-Phillips said that the life sciences sector employed 22,000 staff and was worth more than $35 billion.

Mr Rich-Phillips said the Melbourne was a hub for life sciences manufacturing and had a streamlined trials approval process with "75 percent of clinical trials approved within 30 days".

Apposite Capital director Dr Eric Shiozaki told the conference that since the global financial crisis of 2009 the US had experienced a fall in the Dow Jones Index, rsing unemployment, a patent cliff and a decline in venture capital, but the Nasdaq Biotechnology Index was "at an all-time high".

Dr Shiozaki said that the impact of changes in the US including the Affordable Care Act provided Australia an opportunity for innovative biology and strong management in new biology and disease, rather than "me too" technologies.

Dr Shiozaki said Australia should leverage its proximity to Asia and noted that phase I trials in Australia were more cost effective and faster compared to the US and Europe and large pharmaceutical companies were increasingly outsourcing their research and development.

The investment conference, sponsored by the Victoria Government and Bergen Capital continues tomorrow October 29 in Melbourne ahead of the Brisbane Ausbiotech Conference from October 30 to November 1, 2013.

CLINUVEL PHARMACEUTICALS

Clinuvel says that a physician-led two-patient pilot study shows that Scenesse (afamelanotide 16mg implant) could offer long term remission from Hailey-Hailey disease.

Clinuvel said that Hailey-Hailey disease, also known as familial benign pemphigus, was a rare, chronic, inherited disorder where epidermal skin cells, or keratinocytes, do not adhere correctly, causing periodic eruption of plaque-like lesions and blisters on areas where skin folds, often on the neck, armpits or groin.

The company said that Hailey-Hailey disease could be very distressing for patients, with outbreaks on the legs and groin leading to immobilization due to the pain of friction and a high risk of skin infection.

Clinuvel said that current treatments, including topical corticosteroids and antibiotics, could manage minor outbreaks, but were seen as ineffective in severe cases and there was no professional consensus on a first-line therapy as no remission has been achieved in these patients.

The company said prevalence was unknown, but reports suggested that there are 20 to 30 affected families in most Western European countries.

The study authors hypothesized that an anti-oxidant effect of afamelanotide in keratinocytes might assist in reducing the effect of Hailey-Hailey disease and published several preclinical observations, based on laboratory work, to support their hypothesis, noting that the “clinical and laboratory results provided a strong rationale for the use of afamelanotide for the treatment of [Hailey-Hailey disease]”.

Clinuvel said that a physician-led, open-label observational study of Scenesse was then conducted in two patients at San Gallicano Hospital in Rome, with both patients receivingd two doses of Scenesse, one at the start of the study and the second after 30 days.

The company said that in both patients lesions were reduced after 30 days and completely resolved after 60, with no disease recurrence until eight months after the withdrawal of treatment.

Clinuvel said that both patients reported an improvement in quality of life and the drug was well tolerated.

The article, entitled ‘Efficacy of the melanocortin analogue Nle4-D-Phe7-alpha-melanocyte-stimulating hormone in the treatment of patients with Hailey–Hailey disease’ was published in Clinical and Experimental Dermatology.

An abstract is available at: http://onlinelibrary.wiley.com/doi/10.1111/ced.12203/abstract.

The published conclusion said: “Afamelanotide is effective for the treatment of skin lesions in [Hailey-Hailey disease].”

Clinuvel chief executive officer Dr Philippe Wolgen said that the company was “well aware of the potential of afamelanotide to treat a number of skin disorders”.

“This research proposes a new avenue for afamelanotide to help treat an expanded group of patients with severe, chronic and rare disorders,” Dr Wolgen said.

Clinuvel said that based on the clinical observations to date it was working with leading Hailey-Hailey disease physicians to arrive at a larger study designed to demonstrate a clinically meaningful effect for patients to achieve long term remission; a life without lesions.

The company said that “perhaps most reassuring from this publication is that Scenesse was well tolerated by these patients, consistent with the drug’s long standing safety profile”.

Clinuvel was up one cent or 0.6 percent to $1.57.

INVION

Invion says it has licenced zafirlukast for asthma and other respiratory conditions from Accolade Pharma for $500,000 to be paid over 12 months.

Invion said the licence was to develop and commercialize all inhaled formulations and applications of zafirlukast for the indications and it would develop the drug as an inhaled, non-steroidal, anti-inflammatory treatment for asthma.

The company said that zafirlukast, to be known as INV104, was a leukotriene receptor antagonist or anti-leukotriene that blocked the action of the cysteinyl leukotriene receptors to reduce inflammation, constriction of the airways and the build-up of mucus in the lungs.

Invion said that the oral formulation of zafirlukast wascurrently marketed as a generic drug as well as by Astrazeneca as Accolate and had become available in the public domain due to the expiry of its original patents, but Accolade Pharma had created a patent strategy to develop non-oral formulations of the drug, aimed at reducing side effects and increasing effectiveness.

The company said that research and development executive vice-president and chief medical officer Dr Mitchell Glass led development of oral Accolate to US Food and Drug Administration approval.

Invion company said it intended to develop INV104 for novel inhaled indications using the US Food and Drug Administration abbreviated 505(b)(2) regulatory pathway.

Invion chief executive officer Dr Greg Collier said “the introduction of zafirlukast into our portfolio as INV104 complements Invion’s existing pipeline of inflammatory and respiratory disease treatments”.

“INV104 represents a potential new inhaled, non-steroidal, anti-inflammatory treatment for asthma, which, similar to INV102 uses a drug with an existing safety profile,” Dr Collier said.

“The development of INV104 will utilise existing knowledge, skills and competencies in the Invion clinical team, while strengthening Invion’s development pipeline and asset commercialization opportunities,” Dr Collier said.

“Having been used in over four million people, there is a large safety database for this drug, and as we know, there continues to be a large unmet need for more effective and accessible asthma therapies,” Dr Collier said.

Dr Collier said that having the INV102 or nadolol and INV104 inhaled programs running in parallel meant the company could leverage intellectual property and strategic efficiencies.

Invion said that Dr Glass led the development and submission of Accolate for Zeneca (now Astrazeneca) to its FDA approval in 1998 and was a substantial shareholder of Accolade Pharma.

The company said that if it had net cash of more than $10 million during the 12 month period, it could accelerate these payments and Accolade would be due royalties of 20 percent of net sales related to the development and commercialization of zafirlukast.

Invion was up 1.3 cents or 14.1 percent to 10.5 cents with 5.7 million shares traded.

ALLIED HEALTHCARE GROUP

Allied 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 60 percent from 10 cents on October 18 to 16 cents on October 25, 2013 and noted an increase in trading volume.

Allied said that one possible explanation was the announcement of the issue of shares “in the over-subscribed rights issue”.

Allied was up half a cent or 3.3 percent to 15.5 cents with 34.5 million shares traded.

MESOBLAST

Mesoblast says JCR Pharmaceuticals Co intends to file for regulatory approval for its mesenchymal stem cell product JR-031 for graft-versus-host disease by March 2014.
Mesoblast acquired the mesenchymal stem cell and the Japan-based JCR as a partner when it bought Osiris earlier this month (BD: Oct 11, 2013).
The company said that if the JCR filing was successful JR-031 would be the first allogeneic cell-based product approved in Japan.
Mesoblast said that JCR had exclusive rights in Japan to manufacture, develop and market its culture-expanded mesenchymal stem cells in connection with the use of haematopoietic stem cells derived from peripheral blood, cord blood or bone marrow in the treatment of haematological malignancies.
The company said that JCR was developing and marketing the culture-expanded JR-031 for the treatment of steroid-refractory graft-versus-host disease in children and adults following bone marrow transplantation.
Mesoblast said that JCR would bear all costs associated with bringing culture-expanded mesenchymal stem cell products to market in Japan for haematological malignancies, and would manufacture and sell the products.
The company said that JCR was required to make milestone payments to Mesoblast on product regulatory filing and approvals, certain payments to Mesoblast for pre-determined thresholds of cumulative net sales, as well as royalties.
Mesoblast said that acute graft-versus-host disease was a potentially life threatening complication in about half of all unrelated-donor bone marrow transplant patients and more than 3,500 such transplants were performed in Japan each year.
Mesoblast chief executive Prof Silviu Itescu said the company was “very pleased with our new partnership with JCR”.
“The planned regulatory filing by JCR facilitates the first commercial launch of our mesenchymal lineage products in Japan, the world’s second largest healthcare market,” Prof Itescu said.
Mesoblast was up eight cents or 1.4 percent to $5.97 with 376,674 shares traded.

ATCOR MEDICAL

Atcor says it has signed a supply contract for more than $US600,000 ($A624,793) of Sphygmocor systems and clinical trial support services to a pharmaceutical company.
Atcor said the pharmaceutical company’s study would be conducted in Germany with a minimum value of $US600,000 for the Sphygmocor non-invasive central aortic blood pressure and arterial stiffness system as well as a pre-negotiated option for expansion.
Atcor chief executive officer Duncan Ross said the company was “pleased to have signed another contract with this leading global pharmaceutical company and particularly encouraged that the systems will be used to assess a new disease state”.
“One of Atcor’s goals has been to expand both the number of companies using Sphygmocor and the range of therapeutic disease areas that employ central aortic blood pressure measurement,” Mr Ross said.
Atcor was up one cent or 6.7 percent to 16 cents with 1.4 million shares traded.

BIODIEM

Biodiem says it has sought approval from the ASX to be suspended from trading on November 8 and delist from the ASX on November 15, 2013.
Biodiem fell 0.2 cents or 5.1 percent to 3.7 cents.

AUSTRALIAN INSTITUTE OF POLICY AND SCIENCE

Professor Ruth Bishop has won the $50,000 Australian Institute of Policy and Science CSL Florey Medal for her work on paediatric rotovirus.

A media release from Science In Public on behalf of the Institute said that in 1973, Prof Bishop, Brian Ruck, Geoffrey Davidson and Ian Holmes at the Royal Children's Hospital and the University of Melbourne's microbiology department found the rotavirus was the cause of an acute gastroenteritis that was hospitalizing 10,000 Australian children every year and killing more than half a million children worldwide.

The media release said that a vaccine was created that the Gates Foundation and the Global Alliance for Vaccines and Immunisation are rolling-out to the world's poorest 30 countries, with a new neo-natal vaccine being trialled in New Zealand and Indonesia with the support of the Gates Foundation.

The media relesase said that the vaccination against gastroenteritis has been part of the National Immunisation Program for all Australian infants since July 2007 and the number of hospital admissions had dropped by more than 70 percent.

The media release said that figures from Bolivia, the first low-income country to take part in the program, show a drop of about three-quarters of all hospitalizations.

Science In Public said that the CSL Florey Medal “honours Australian researchers who have made significant achievements in biomedical science and/or in advancing human health” and was presented every two years.