Biotech Daily

Friday February 12, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ORTHOCELL UP 6%, IDT DOWN 12%**

*** FDA FURTHER ORPHAN STATUS FOR CLINUVEL SCENESSE**

*** VIBURNUM, WYLLIE FUNDS TAKE 11% OF UNIVERSAL BIOSENSORS**

*** VICTORIA APPOINTS 2nd INNOVATION PANEL – LIGHT ON BIOTECH**

*** BLUECHIIP READY FOR GENEA IVF PRODUCT DEVELOPMENT**

*** ATCOR H1 REVENUE DOWN 41% TO $1.7m, PROFIT TO $2.3m LOSS**

*** POLYNOVO EXPECTS INCREASED H1 LOSS**

MARKET REPORT

The Australian stock market retreated 1.16 percent on Friday February 12, 2016 with the ASX200 down 55.8 points to 4,765.3 points.

Seven of the Biotech Daily Top 40 stocks were up, 24 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Orthocell was the best, up 2.5 cents or 6.2 percent to 43 cents with 158,082 shares traded.

Cellmid climbed 5.3 percent; Medical Developments was up 3.75 percent; Oncosil rose 2.6 percent; Bionomics and Osprey were up more than one percent; with Impedimed up 0.6 percent.

IDT led the falls, down 3.5 cents or 12.1 percent to 25.5 cents with 690,244 shares traded, followed by Atcor down 10.5 percent to 17 cents with 475,321 shares traded.

Actinogen lost 9.1 percent; Antisense and Optiscan fell more than eight percent; Admedus and Neuren were down more than seven percent; Starpharma shed 6.8 percent; Biotron, Ellex, Genetic Technologies and Pharmaxis fell five percent or more; Compumedics, Prana and Prima were down four percent or more; Sirtex was down 3.3 percent; Viralytics shed 2.05 percent; Living Cell, Mesoblast, Opthea, Pro Medicus and Resmed were down more than one percent; with Acrux, Cochlear, CSL, Nanosonics and Reva down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says that the US Food and Drug Administration has granted orphan drug designation for Scenesse (afamelanotide 16mg) for cutaneous variants of porphyria.
Clinuvel said that the designation “recognizes the potential of afamelanotide to treat or prevent symptoms in rare forms of porphyria and offers incentives to Clinuvel to develop the drug for these patients”.
The company said that previously, Scenesse had been granted orphan designation by the FDA for erythropoietic protoporphyria and congenital erythropoietic porphyria.
Clinuvel said that Scenesse had been evaluated as a photo-protective drug in a severe form of porphyria, erythropoietic protoporphyria (EPP), for which it had marketing authorisation in Europe and was approved as an orphan medicinal product in Europe for the prevention of photo-toxicity in adult patients with EPP.
Clinuvel said that Scenesse might have a photo-protective effect for patients with other rare forms of cutaneous porphyria, including variegate porphyria, hereditary coproporphyria and congenital erythropoietic porphyria (CEP).
The company said that porphyrias were a family of seven genetic metabolic disorders which caused malfunctions in the haeme biosynthetic pathway.
Clinuvel said that while classically grouped together, each of the five cutaneous porphyrias had clinically distinct symptoms, generally characterized as acute dermal reactions affecting the skin and anaphylactoid in nature, which were caused by the accumulation and storage of phototoxic molecules, or porphyrins, in the body.
The company said that when patients with cutaneous porphyria exposed their skin to visible light, including sunlight and certain artificial lights, the porphyrins reacted causing symptoms such as oedema and deep burns leading to damage of soft tissue and scarring.
Clinuvel said that patients were conditioned from childhood to withdraw from light and sun exposure to prevent photo-toxicity, resulting in light starvation and social isolation.
The company said no cutaneous porphyria trials were currently planned, but it was working to make Scenesse available to patients with CEP on a named-patient basis.
Clinuvel said that only a few hundred cases of CEP had been recorded in the literature.
The company said the FDA granted orphan-drug designation to drugs which had the potential to diagnose or treat rare conditions, affecting fewer than 200,000 US individuals.
Clinuvel said the additional designation entitled it to technical assistance throughout the development process for cutaneous porphyrias, potential fee reductions and tax credits, and seven years’ market exclusivity if approved for marketing by the FDA.
Clinuvel acting chief scientific officer Dr Dennis Wright said that “beyond EPP we have always recognized that patients with other forms of cutaneous porphyria are deeply affected by their condition”.
“The FDA’s designation acknowledges the potential of afamelanotide to assist those patients,” Dr Wright said.
Clinuvel was unchanged at $3.00.

UNIVERSAL BIOSENSORS

Viburnum Funds says it has increased its substantial holding in Universal Biosensors from 16,431,603 Chess depositary interests (9.36%) to 18,993,656 shares (10.82%).
The Perth, Western Australia-based Viburnum notice said the holders included Wyllie Funds Management, Wyllie Group and Rhonda Wyllie along with JP Morgan as a registered holder and between December 8, 2015 and February 11, 2016 the funds acquired 2,562,053 shares for $1,069,270 or 41.7 cents a share
Universal Biosensors was unchanged at 39.5 cents.

VICTORIA GOVERNMENT

The Victoria Government says it has an appointed Innovation Expert Panel to strengthen the State's position as Australia's innovation and technology hub.

The 15-member panel includes just one person known in the biotechnology sector, the Small Technology Cluster's chief executive officer Dr Buzz Palmer, along with Mercer Capital managing director Emily Lee who has been appointed as a director to the Taiwan-controlled TBG Diagnostics, formerly the Brisbane-based Progen.

Two weeks ago the Victoria Government has appointed the 10-member $60 million Launchvic board "to drive innovation", with just one appointment known to the biotechnology sector, former Circadian chair Dominique Fisher (BD: Jan 29, 2016).

Today, the Minister for Small Business, Innovation and Trade Philip Dalidakis said the Government "had secured some of the country's leading innovators, company directors and [chief executive officers], with women again dominating the panel's make-up".

A media release from Mr Dalidakis said that two-thirds of the appointed panel would be entrepreneurs "with experience in turning bright ideas into commercial realties and they will share the table with some of the country's key drivers of technology innovation from the university and private sectors".

The Government said the Innovation Expert Panel would "analyze and provide advice about new models for innovation, emerging trends and issues, disruptive technologies and their potential to impact business growth across all industry sectors".

The media release said that Victoria's lead scientist Dr Leonie Walsh would chair the panel, with other members including Zendesk managing-director Brett Adam, IBM Research Australia's laboratory director Dr Joanna Batstone, 2Mar Robotics founder Marita Cheng, Rision managing-director Dr Kate Cornick, Intelligencebank chief executive officer Tessa Herd Court, Curve Tomorrow principal Mohinder Jaimangal, Onestack co-founder Jonathan Jeffries, Ms Lee, Nitro Asia-Pacifice director Adam Nowiski, Dr Palmer, Huddle founder Dr Melis Senova, QSR International chief executive officer Kerri Lee Sinclair, Differential managing partner Chris Thomas and Data61 chief executive officer Adrian Turner.

BLUECHIIP

Bluechiip says it has completed concept due diligence for tracking Genea Biomedx assisted reproductive technology and will progress to product development.

Last year, Bluechiip said that the Sydney-based Genea had a licence to incorporate Bluchiip sample tracking technology into Genea's assisted reproductive technology instruments (BD: Dec 3, 2015).

Today, Bluechiip chief executive officer Andrew McLellan said the company was "excited to be moving to the development phase with the achievement of this milestone".

"It is a very significant step for Bluechiip," Mr McLellan said.

"Our ability to work with partners to incorporate our technologies is fundamental to our strategy and in the field of [assisted reproductive technology and in-vitro-fertilization] we are successfully working to incorporate our technologies into partner's products," Mr McLellan said.

Last year, Bluechiip said that Genea would licence the wireless tracking technology designed for -196oC cryogenic temperatures for assisted reproductive technology and the licence and supply would progress through staged development phases including concept due diligence, product development and subsequent commercial release.

The company said the licence included milestone payments and minimum quantities.

Bluechiip was up 0.4 cents or 13.3 percent to 3.4 cents.

ATCOR MEDICAL

Atcor says its revenue for the six months to December 31, 2015 fell 40.8 percent to $1,691,491 taking the previous $41,451 net profit after tax to a loss of $2,297,946.
Atcor said that sales were lower than expectations due to delays in finalizing a new client pharmaceutical contract, with sales and services in the Americas to the pharmaceutical industry and to researchers and clinicians, significantly lower than the prior corresponding period.
The company said that no new pharmaceutical sector contracts were written in the half year, and sales to researchers and clinicians declined as research projects, which included three one-off multi-system sales, were not repeated.
Atcor said that in Europe, the Middle East and Africa, sales declined 23 percent, but Asia Pacific sales were up grew 22 percent driven by growth in Australia and New Zealand.
Atcor said that its net tangible asset backing per share fell 8.7 percent from 2.3 cents at December 31, 2014 to 2.5 cents at December 31, 2015.
The company said that said that diluted loss per share was 1.17 cents compared to the previous corresponding period's diluted earnings per share of 0.02 cents.
Atcor said it held cash and cash equivalents of $3,784,442 at December 31, 2015 compared to $3,449,943 at June 30, 2015.
Atcor fell two cents or 10.5 percent to 17 cents.

POLYNOVO

Polynovo says the loss after tax for the six months to December 31, 2015 is expected to be in the range of $2.3 million to $2.4 million.
Polynovo said that the increased loss, compared to loss of $1.44 million for the six months to December 31, 2014 was predominantly due to research, development and consultancy costs associated with the US Biomedical Advanced Research and Development Authority project and Conformité Européenne (CE) Mark trials.
The company said that in the six months to December 31, 2015 it had raised $12.9 million and held $13.4 million in cash and short term investments.
Polynovo was unchanged at 27 cents.