Biotech Daily

Wednesday February 14, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: AVITA UP 7%; USCOM DOWN 8%**

*** CSL RECORD H1 REVENUE UP 13% TO $5.3b, PROFIT UP 35% TO $1.4b**

*** BIONOMICS H1 REVENUE UP 0.4% to $7m, LOSS DOWN 9% TO $9m**

*** USCOM H1 REVENUE DOWN 25% TO $2m, LOSS UP 28% TO $1.1m**

*** PATRYS RIGHTS ISSUE RAISES $2.4m**

*** EMA GRANTS REGENEUS PROGENZA ADVANCED THERAPY STATUS**

*** NUHEARA, SONOVA BEGIN IQBUD HEARING HEALTH SALES TRIAL**

*** CRESO KUNNA ACQUISITION DUE DILIGENCE EXPECTED IN MARCH**

*** CULT BEAUTY LAUNCHES MGC MARIJUANA COSMETICS**

*** ALCIDION TO RELEASE 249m SHARES, 218m RIGHTS FROM ASX ESCROW**

*** HYPERION BELOW 5% OF COCHLEAR**

MARKET REPORT

The Australian stock market fell 0.25 percent on Wednesday February 14, 2018 with the ASX200 down 14.7 points to 5,841.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and two were untraded.

Avita was the best, up 0.4 cents or 6.7 percent to 6.4 cents with 7.4 million shares traded. CSL climbed 5.1 percent; Bionomics, Dimerix and Opthea improved more than four percent; Clinuvel and Cyclopharm were up more than three percent; Benitec, Cochlear, Factor Therapeutics and Mesoblast rose more than two percent; ITL, Osprey, Prana and Starpharma were up more than one percent; with Psivida and Sirtex up by less than one percent.

Uscom led the falls for the second day in a row, down two cents or eight percent to 23 cents with 65,655 shares traded. Orthocell fell 7.5 percent; Genetic Signatures lost 6.8 percent; Actinogen, Impedimed and Volpara were down more than three percent; Ellex, LBT and Medical Developments shed more than two percent; Admedus, Nanosonics, Polynovo, Pro Medicus and Universal Biosensors were down more than one percent; with Neuren down 0.3 percent.

CSL

CSL's revenue for the six months to December 31, 2017 up 12.8 percent to $US4,146.6 million ($A5,273.1 million) with net profit after tax up 34.9 percent to a record $US1,086.3 million ($A1,381.6 million).

CSL said that research and development expenditure increased 19.5 percent to $US342.9 million for the six months to December 31, 2017 or 8.3 percent of total revenue, compared to 7.8 percent for the six months to December 31, 2016.

The company said that diluted earnings per share was up 35.8 percent to $US2.39 and it had cash and cash equivalents of $US849.6 million at December 31, 2017 compared to $US884.5 million at December 31, 2016.

CSL said an interim unfranked dividend, up 23.4 percent to 79.0 US cents, would be paid on April 13, for a record date of March 15, 2018.

CSL chief executive officer Paul Perreault told an internet and teleconference that immunoglobulin sales were up 13 percent on the previous six months in constant currency with Haegarda and Idelvion performing well along with speciality products.

Mr Perreault said that Privigen had been approved for chronic inflammatory demyelinating polyneuropathy (CIPD) in the US and there was a positive recommendation for EU approval of Hizentra for CIPD.

Mr Perreault said the company was making "very good progress" with its Seqirus influenza assets and CSL Behring had continuing growth up 8.1 percent compared to the previous corresponding period, with Idelvion for haemophilia B sales strong in the US and Japan, and along with Afstyla for haemophilia A, launched in 13 countries.

Mr Perreault said that Haegarda for hereditary angioedema attacks was "transforming patients' lives" following the US launch with a 95 percent reduction in attacks and 99 percent reduction in rescue medication use, and sales of Kcentra plasma for warfarin reversal was up 32 percent on the previous corresponding period.

Mr Perreault said the company was increasing efficiencies in plasma collection, had embarked on major capital projects at Broadmeadows in Victoria, as well as the Kankakee fractionation facility in Illinois and the Seqirus plant in Holly Springs, North Carolina.

He said that other developments included the Calimmune acquisition for stem cell and gene therapies, with CSL112 to reduce cholesterol and stabilize atherosclerotic plaques to prevent secondary major adverse cardiovascular events expected to begin a phase III trial by July 2018 and CSL730 for autoimmune diseases in a phase I safety trial.

Mr Perreult said the outlook for the year to June 30, 2018 was an expected net profit after tax of $US1.55 billion to $US1.6 billion, with an expected Seqirus loss in the second half of the year.

CSL was up $7.22 or 5.1 percent to $149.29 with 1.9 million shares traded.

BIONOMICS

Bionomics says that revenue for the six months to December 31, 2017, was up 0.4 percent to $7,168,539 with net loss after tax down 8.8 percent to $8,846,833.

Bionomics said that revenue included collaboration income, royalties, sales, rental and interest income, along with government grants and the R&D Tax Incentive.

The company said that diluted loss per share fell 10 percent to 1.8 cents for the six months to December 31, 2017 and net tangible asset backing per share fell 9.4 percent from 5.3 cents at December 31, 2016 to 4.8 cents at December 31, 2017.

Bionomics said it had cash and cash equivalents of $32,021,177 at December 31, 2017 compared to $43,122,288 at December 31, 2016.

Bionomics was up 1.5 cents or 4.3 percent to 36.5 cents.

USCOM

Uscom says that revenue for the six months to December 31, 2017, fell 25.1 percent to $1,422,974 with net loss after tax up 28.2 percent to $1,084,420.
Uscom said that sales were down 61 percent in the three months to September 30, 2017 “due to restrained China economic activity”, but rebounded by 102 percent with record orders for the Uscom 1A ultra-sonic cardiac output monitor.
The company said that it expected revenues “thought lumpy, to remain on a continued upward trend” enhanced by approvals for its BP+ central blood pressure diagnostic and its Spirosonic lung function test.
Uscom said that diluted loss per share increased 12.5 percent from 0.8 cents at December 31, 2016, to 0.9 cents at December 31, 2017, with cash and cash equivalents of $3,487,644 at December 31, 2017 compared $1,880,517 at December 31, 2016.
The company said that net tangible asset per share was up 17.9 percent to 3.3 cents.
Uscom fell two cents or eight percent to 23 cents.

PATRYS

Patrys says it has raised $2.4 million it its fully-underwritten, non-renounceable two-for-11 rights issue at 1.7 cents a share.
Patrys said the rights issue was 45 percent oversubscribed.
In January, Patrys said the funds would be used to accelerate development of the Deoxymab platform, further business development of the Immunoglobulin M platform, ancillary other developments, operations, insurance claim prosecution, corporate activities and working capital (BD: Jan 21, 2018).
Patrys was unchanged at 2.3 cents with 1.7 million shares traded.

REGENEUS

Regeneus says the European Medicines Agency has granted its fat-derived Progenza an advanced therapy medicinal product classification.
Regeneus said that the Agency’s Committee for Advanced Therapies approved the classification following consultation with the European Commission.
The company said that Progenza was its allogeneic stem cell technology for osteoarthritis and other inflammatory conditions.
Regeneus chief executive officer John Martin said the grant was “a step towards bringing Progenza to Europe as a novel cell therapy treatment for osteoarthritis”.
Mr Martin told Biotech Daily that the advanced therapy medicinal product (ATMP) designation was set up to regulate new cell, gene and tissue cultured products, providing a benchmark for a level of quality compliance for pharmaceutical practices.
“The regulation provides helpful guidelines to developers for non-clinical and manufacturing development as well as product testing,” Mr Martin said.
“It also provides incentives to companies involved in developing ATMPs through a local [European union] subsidiary including fee reductions for scientific advice, scientific recommendations on ATMP classification and evaluation and certification of quality and non-clinical data,” Mr Martin said.
The company said that the classification was for new regenerative therapies that combined medicine, cell biology, science and engineering for regenerating, repairing or replacing a human tissue, comprising cell and gene therapies and tissue-engineered products.
Regeneus was unchanged at 12.5 cents.

NUHEARA

Nuheara says it will begin a three-month sales trial of its Iqbud sound filtering and device ear buds for hearing health, through Sonova owned hearing aid outlets.

Nuheara said that the Sydney metropolitan area trial would be through hearing aid retail shops Hearing Planet and Connect Hearing both owned by the Stäfa, Switzerland-based Sonova, which said it was "the leading provider of innovative hearing care [rpoducts]".

Nuheara chief executive officer Justin Miller said it was "well-reported that 15 percent of all adults have some degree of hearing impairment".

"What is largely unknown is that only 20 percent of those hearing-impaired adults have then actually purchased any form of hearing system to offset the impairment," Mr Miller said.

Mr Miller said his company's hearing health products were "designed to provide accessibility and affordability for these hearing challenged consumers, in particular for those with mild to moderate hearing loss who represent the majority that go without any hearing assistance".

"We are delighted to welcome Hearing Planet and Connect Hearing into the sales fold for a focused trial targeting these consumers," Mr Miller said.

Nuheara fell 0.4 cents or 6.25 percent to six cents with four million shares traded.

CRESO PHARMA

Creso says that due diligence for its acquisition of Kunna Canada and its Colombian subsidiary Kunna SAS is expected to be completed in March 2018.

Creso said that Kunna's application for a licence to cultivate medicinal cannabis had been completed and the licence was expected to be granted in April 2018.

The company said that a completed acquisition would provide "a foothold in the strategically important Latin American market … [and make it] the only Australian-listed medicinal cannabis company with direct exposure to the Colombian market and with the capacity to commercially cultivate medicinal-grade cannabis in that country".

Creso said that Colombia legalized medicinal cannabis in 2016 and a 2017 decree provided for grower licences, cannabis-based drug manufacturing and export permits.

The company said the Colombia was "a significant market opportunity" with up to six million patients.

Creso said that Kunna was granted a licence to produce, manufacture, market and export cannabis derivatives and products on March 31, 2017 and had applied for a licence to cultivate medicinal cannabis which it expected to be granted in April 2018.

Creso chief executive officer Dr Miri Halperin Wernli said the acquisition and cultivation licence would "give Creso a significant competitive advantage as [it] will be one of the few companies … with the capacity to commercially cultivate medicinal-grade cannabis in this strategic and growing market".

Creso fell four cents or 3.9 percent to 98 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says London's Cult Beauty has launched its range of MGC Derma and Derma Plus marijuana-cosmetics through its online sales platform (BD: Jan 22, 2018).

MGC said that 15 of its cannabidiol cosmetic products and its Derma plus skin care range would be on sale at Cult Beauty in the UK and around the world, as legally permitted.

The company said that Cult Beauty would run a six-month marketing campaign.

MGC was unchanged 11 cents with seven million shares traded.

ALCIDION GROUP

Alcidion says it will release 248,714,874 ordinary shares, 107,827,957 class A share rights and 110,322,219 class B share rights from ASX escrow on March 1, 2018.
Alcidion said the majority of the shares were held by founders or related parties.
The company said that executive chairman Raymond Blight and executive director Malcolm Pradhan had 219,056,883 shares coming out of escrow, but did not “have any current intention of disposing of these shares”.
Alcidion said that a further 2,458,828 shares held by Allure Capital would be released from voluntary escrow on March 1, 2018.
Alcidion fell 0.2 cents or 4.35 percent to 4.4 cents.

COCHLEAR

The Brisbane-based Hyperion Asset Management says it has reduced its holding in Cochlear from 3,472,955 shares (6.05%) to below substantial.
Hyperion said that between November 24 2016 and February 12, 2018 it sold 616,801 shares for $109,765,585 or an average price of $177.96 per share, implying that it retained 2,856,154 shares or 4.96 percent (BD: Nov 29, 2016).
In 2016, Hyperion said the registered holders included JP Morgan Chase Nominees, BNP Paribas, Citibank Nominees, National Nominees, RBC Investor Services and individually managed accounts with relevant interests held by 20 superannuation funds, trusts and entities, adding the Bank of New York Mellon today.
Cochlear was up $4.25 or 2.5 percent to $175.99 with 251,599 shares traded.