Biotech Daily

Wednesday February 13, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: BENITEC UP 38%; COMPUMEDICS DOWN 7%**

*** CSL RECORD H1 REVENUE UP 9% TO $6.3b, PROFIT UP 7% TO $1.6b**

*** ORTHOCELL: 'ORTHO-ATI 82% SUCCESS'**

*** INVICTUS REQUESTS FDA LIVER, PANCREAS DRUGS MEETING**

*** MAYNE TO SELL LEXETTE FOR PSORIASIS IN US**

*** CROSS-PARTY LAUNCH OF MEDICINAL CANNABIS INDUSTRY AUSTRALIA**

*** CRESO: BURLEIGH HEADS TO DISTRIBUTE MEDICAL MARIJUANA**

*** ESENSE 80% DUMP CEO HAIM COHEN AS DIRECTOR**

*** PAINCHEK PLEADS SCHULTZ, 'PUBLICITY' TO ASX 71% QUERY**

*** RACE CHAIR DR WILLIAM GARNER REDUCES TO 15.8%**

*** FIL REDUCES TO 7.1% OF ADHERIUM**

MARKET REPORT

The Australian stock market fell 0.25 percent on Wednesday February 13, 2019, with the ASX200 down 15.5 points to 6,063.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded.

Benitec was the best on no news, up four cents or 38.1 percent to 14.5 cents with 1.0 million shares traded.

Airxpanders climbed 12.5 percent; Orthocell was up 10 percent; Paradigm and Patrys improved more than eight percent; Avita rose 7.4 percent; Imugene was up 5.9 percent; Nanosonics and Pro Medicus were up more than four percent; Cynata improved 3.5 percent; Clinuvel, Impedimed and Prana rose more than two percent; Kazia, Optiscan and Pharmaxis were up more than one percent; with Resmed up 0.1 percent.

Compumedics led the falls, down 2.5 cents or seven percent to 33 cents, with 9,790 shares traded. CSL, Genetic Signatures and Immutep lost more than three percent; Antisense, Cochlear, Dimerix, LBT and Reva shed more than two percent; Actinogen, Ellex, Neuren, Prescient and Telix were down more than one percent; with Mesoblast down 0.85 percent.

CSL

CSL's revenue for the six months to December 31, 2018 up 8.6 percent to $US4,504.8 million ($A6,345.3 million) with net profit after tax up 6.85 percent to $US1,160.7 million ($A1,634.9 million).

CSL said that research and development expenditure increased 14.0 percent to $US391.0 million for the six months to December 31, 2018 or 8.7 percent of total revenue, compared to 8.3 percent for the six months to December 31, 2017.

The company said that diluted earnings per share was up 6.7 percent to $US2.55 and it had cash and cash equivalents of $US644.9 million at December 31, 2018 compared to $US841.1 million at December 31, 2017.

CSL said that an interim unfranked dividend, up 7.6 percent to 85.0 US cents, would be paid on April 12, for a record date of March 14, 2019.

CSL chief executive officer Paul Perrault told an internet and teleconference that immunoglobulin sales were up 12 percent on the previous six months in constant currency, with haemophilia product sales down two percent, albumin sales down four percent, but volume was up three percent and specialty products were up 13 percent.

Mr Perreault said that Privigen sales were up 17 percent, the Seqirus influenza assets revenue was up 21 percent, CSL Behring was up eight percent, with Idelvion for haemophilia B sales strong in the US and Japan, up 55 percent and Afstyla for haemophilia A, launched in 14 countries and adopted by more than 500 patients.

Mr Perreault said that sales for Haegarda for hereditary angioedema attacks tripled and sales of Kcentra plasma for warfarin reversal were up 19 percent and 23 percent in the US on the previous corresponding period.

Mr Perreault said the company was increasing efficiencies with a $US46 million research facility in Melbourne, the progression of major capital projects and new enterprise resource planning systems, implemented across CSL Behring and Seqirus in the US and the EU and to be rolled out in the Asian Pacific region.

He said other developments included Australian approval of Hizentra for chronic inflammatory demyelinating polyneuropathy (CIDP), five new products in clinical human trials and continuing recruitment for CSL112 to reduce cholesterol and stabilize atherosclerotic plaques to prevent secondary major adverse cardiovascular events.

Mr Perreault said the outlook for the year to June 30, 2019 was an expected net profit after tax of $US1.88 billion to $US1.95 billion, with an expected Seqirus loss in the second half of the year.

CSL fell $7.60 or 3.9 percent to $186.09 with 2.1 million shares traded.

ORTHOCELL

Orthocell says its autologous tenocyte implantation (Ortho-ATI) stem cell therapy for the treatment of chronic tendon injuries has shown an 82 percent success rate.

Orthocell said 47 patients were treated for an average 23 months for gluteal, elbow, shoulder, Achilles, knee and hamstring tendon injuries, prior to completing the questionnaire.

The company said that 38 of 46 responding patients (82.6%) said they were 'satisfied' or 'extremely satisfied' with how Ortho-ATI relieved pain symptoms and 37 patients of 46 respondents (80.4%) said they were 'satisfied' or 'extremely satisfied' with how it improved their ability to perform everyday activities.

Orthocell said that 37 patients of 45 responding patients (82.2%) were 'satisfied' or 'very satisfied' overall with Ortho-ATI.

Orthocell was up 1.5 cents or 10 percent to 16.5 cents.

INVICTUS BIOPHARMA

Invictus says it has submitted a formal request to the US Food and Drug Administration for a pre-investigational new drug consultation.
Invictus said that the submission outlined the rationale behind its drug development program to develop therapies for non-alcoholic fatty liver disease, non-alcoholic steatohepatitis and pancreatic cancer.
The company said that consultation with the FDA was expected to be completed in the next two months.
Invictus said that the meeting request outlined the proposed pathway to develop two drug candidates, one targeting non-alcoholic fatty liver disease (NAFLD) and the later stage non-alcoholic steato-hepatitis (NASH) and the other targeting pancreatic cancer, based on the company's "patented transmucosal drug delivery platform".
The company said that the pre-IND submission proposed two protocols for two phase II proof of concept clinical studies, one for NAFLD and NASH and the second for pancreatic cancer.
Invictus said the submission outlined how a direct and non-invasive method for delivering vitamin E-derived tocotrienols would improve the bioavailability of the drug to provide a treatment for NAFLD, NASH and pancreatic cancer.
The company said that the submission addressed safety and toxicity from animal and clinical studies and set out manufacturing methods for the drugs.
Invictus chief scientific officer Dr David Kingston said that "guidance from the FDA in relation to our drug development program is critical as the US is a high priority market for all of our drug candidates".
The company said that a number of published studies using orally-administered tocotrienols to address NAFLD and NASH had shown promise and animal studies have shown that tocotrienols had the potential to target pancreatic and other cancers in a novel way.
Invictus said that it was estimated between 75 million to 100 million people in the US were affected by NAFLD and NASH with the number affected increasing, with no medicines approved for the treatment of either indication, which were associated with insulin resistance and the metabolic syndrome, hyperlipidaemia, diabetes and high blood pressure.
The company said that the majority of pancreatic cancer diagnoses were at the advanced stages of the disease and consequently it was the fourth leading cause of cancer-related deaths in the US, claiming an estimated 44,000 lives each year.
Invictus said it intended to apply for orphan drug status for its pancreatic cancer drug candidate when it opened an investigational new drug application prior to US-based clinical studies.
The company said there were a number of medicines and radiotherapy approved for the treatment of pancreatic cancer but they mostly produce relatively short-lived remissions.
Invictus is a public unlisted company.

MAYNE PHARMA GROUP

Mayne says it has launched Lexette, or halobetasol propionate, in the US for plaque psoriasis in adults.
Mayne said Lexette was a potent topical corticosteroid for the treatment of plaque psoriasis, which affects 7.5 million Americans.
Mayne was up 3.5 cents or 4.3 percent to 84.5 cents with 6.1 million shares traded.

MEDICINAL CANNABIS INDUSTRY AUSTRALIA

The Medicinal Cannabis Industry Australia says it will be launched tonight by Federal Health Minister Greg Hunt, with support from the Labor Party and the Greens.

The MCIA chairman, and Cann Group chief executive officer, Peter Crock told Biotech Daily that Labor shadow agriculture minister Joel Fitzgibbon, representing Labor shadow health minister Catherine King, and Greens leader Senator Dr Richard di Natale would address the meeting.

A media release from the industry association said it was formed “to foster health and a sustainable industry”.

The Medicinal Cannabis Industry Australia (MCIA) said that Australia’s medicinal cannabis industry licencees were “coming together to form a national advocacy body to support the fledgling industry achieve health and economic benefits”.

Mr Crock told Biotech Daily that the MCIA was aware that despite all the regulatory approvals patients were unable to go to doctors for a prescription for medical marijuana which could be filled by local chemists.

“The industry organization accepts that patient access is not happening as quickly as we would like,” Mr Crock said.

“It is a priority for us,” Mr Crock said.

In the media release Mr Crock said it was “important that those engaged in the new sector worked together to build a professional and well-respected association to represent the best of Australian industry”.

“MCIA members are committed to ensuring medicinal cannabis products meet the highest standards and that patients in Australia and internationally benefit from research and product development,” Mr Crock said.

“As medical research increases and more countries regulate for the use of medicinal cannabis we can see the importance of what is effectively a new class of compound in medicine,” Mr Crock said.

“It is almost three years since the Australian Parliament passed legislation, on February 29, 2016, to enable the cultivation of cannabis for medicinal and research purposes,” Mr Crock said.

“With regulators and operators having started from scratch, the industry has already come a long way, and Australia aims to become a world leading supplier of medicinal cannabis products in the coming years,” Mr Crock said.

“MCIA recognizes that there are a diverse range of stakeholders and views held within the community about the use of medicinal cannabis and believes the industry has an obligation to engage with policy makers about the benefits the industry can provide for the health and wealth of Australia,” Mr Crock said.

“The best way to do this is to make sure the industry behaves in a transparent, responsible and professional manner across all activities including research, cultivation, manufacturing and education,” Mr Crock said.

“An industry that is built on sound science and underpinned by best practice standards will help ensure that patients, medical professionals, governments and the community have confidence in us and our products,” Mr Crock said.

Mr Crock said that the group’s members were “working to enhance wellbeing by making quality Australian medicinal cannabis products available for patients here and around the world”.

The media release said that MCIA’s founding members were Cann Group, Auscann, Cronos Australia, THC Global, Medreleaf Australia and Althea Co.

CRESO PHARMA

Creso says it has a letter of intent with Queensland's Burleigh Heads Cannabis to expand distribution of its medicinal marijuana products into Australia.
Creso said Burleigh Heads was a subsidiary of Cannabis Doctors Australia (CDA), which supported patient access to medical marijuana through its branded products and clinics.
The company said it would initially focus on gaining regulatory approval of its Cannaqix50, to be sold in Australia as CDA CBD 50 Lozenges.
Creso said that pending regulatory approvals it would enter a comprehensive distribution agreement with Burleigh Heads within the next month.
Creso was up one cent or 2.7 percent to 38.5 cents.

ESENSE-LAB

Esense investors have voted chief executive officer Haim Cohen off the board with 25,130,818 votes (80.2%) opposing his re-election and 6,193,263 votes (19.8%) in favor.
Director Benjamin Karasik faced 32.8 percent opposition to his re-election, with directors Piers Lewis and Amit Edri re-elected with more than 30.6 million votes in favor and more than 708,000 votes against.
The issue of 400,000 options for Jakob Zecharia was passed with 20.9 million votes in favor and 7.2 million votes against, with the placement capacity and change of accountant approved by a wider margin.
According to the most recent Esense Appendix 3B new issue announcement the company had 185,676,917 shares on issue, meaning the vote against Mr Cohen amounted to 13.5 percent of the company, sufficient to requisition extraordinary general meetings.
Esense company secretary Ian Pamensky told Biotech Daily that the board was reviewing Mr Cohen's position following the vote.
Esense fell 0.1 cents or 3.6 percent to 2.7 cents with 5.4 million shares traded.

PAINCHEK

Painchek 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 two cents or 71.4 percent from 2.8 cents on February 7, 2019 to 4.8 cents on February 12, 2019 and noted a "significant increase" in trading volume.
Painchek said reports on the Australian Aged Care Royal Commission had generated publicity for the company and a video of managing-director Phillip Daffas discussing the company was in circulation.
Painchek fell 0.7 cents or 15.6 percent to 3.8 cents with 2.55 million shares traded.

RACE ONCOLOGY

William James Garner says he has reduced his holding in Race Oncology from 14,405,916 shares (17.52%) to 12,981,741 shares (15.79%).
Mr Garner said that in an off-market transfers between December 24, 2018 and February 8, 2019, he transferred 1,424,175 shares for no consideration.
Race was up 0.2 cents or 2.4 percent to 8.4 cents.

ADHERIUM

FIL Limited says it has reduced its holding in Adherium from 14,745,815 shares (8.46%) to 12,400,096 shares (7.12%).

FIL said that on February 7 and 8, 2019 it sold 2,345,719 shares for 2.29 cents and 2.3 cents a share.

Last week, FIL said it had reduced its holding in Adherium by 1,980,780 shares to 8.46 percent of the company (BD: Feb 11, 2019).

Adherium was unchanged at 2.4 cents.