Biotech Daily

Wednesday February 3, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 10%, OPTISCAN DOWN 15%**

*** VICTORIA, AUSTIN JOIN CANNABIS FOR PAEDIATRIC EPILEPSY TRIAL**

*** ETHICS APPROVAL FOR LIVING CELL NTCELL PARKINSON'S TRIAL**

*** ONCOSIL RAISES $10m, AGAIN, FOR PHASE III PANCREATIC CANCER TRIAL**

*** ADMEDUS CLAIMS FIRST MIDDLE EAST CARDIOCEL SALES**

*** DORSAVI SIGNS TOYOTA UK, JAGUAR LAND ROVER FOR VISAFE**

*** GOODBYE PROGEN, WELCOME TBG AT A 26% PREMIUM**

*** ALLAN GRAY FURTHER REDUCES TO 4% OF ALCHEMIA**

*** SANDON CAPITAL TAKES 19% OF ALCHEMIA**

*** ADAM GALLAGHER REPLACES AGENIX CO SEC GARY TAYLOR**

MARKET REPORT

The Australian stock market fell 2.33 percent on Wednesday February 3, 2016 with the ASX200 down 116.5 points to 4,876.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and three were untraded.

Cellmid was the best, up 0.2 cents or 10 percent to 2.2 cents with 735,265 shares traded.

Antisense climbed 7.1 percent; Living Cell was up 5.8 percent; Admedus and Tissue Therapies rose more than four percent; Biotron improved 3.1 percent; Opthea and Prima rose more than two percent; with Acrux, Medical Developments, Pro Medicus and Resmed were up one percent or more.

Optiscan led the falls, down 0.4 cents or 15.4 percent to 2.2 cents with 879,881 shares traded, followed by Orthocell down 10.5 percent to 47 cents with 411,195 shares traded.

Atcor lost 7.9 percent; Pharmaxis, Starpharma and Uscom fell more than six percent; Ellex was down 5.3 percent; Compumedics fell 4.9 percent; Bionomics and Clinuvel were down more than three percent; CSL, Mesoblast, Psivida, Sirtex and Universal Biosensors shed two percent or more; Actinogen, Cochlear, Impedimed and Nanosonics lost one percent or more; with Viralytics down 0.6 percent.

VICTORIA GOVERNMENT

The Victoria Government says it and Austin Health will take part in an international clinical trial of a US developed synthetic cannabidiol for childhood epilepsy.

A media release from Victoria Premier Daniel Andrews and Minister for Health Jill Hennessy said that Austin Health had agree to be part of a clinical trial of the cannabidiol developed by the Chandler, Arizona-based based Insys Therapeutics to treat paediatric patients with refractory epilepsy.

The State Government said that the trial was investigating whether the medicine would be effective in treating certain types of childhood epilepsy and would investigate appropriate dosages within a small group of patients.

The Government said that in Australia the trial would be led by Austin Health's director of paediatrics Prof Ingrid Scheffer, whose research group was the first to uncover a gene for epilepsy.

A spokesperson for Austin Health said that the trial protocol was subject to a confidentiality agreement with the company, but was expected to be posted to www.clinicaltrials.gov "soon".

Ms Hennessy said that "by supporting this trial we are working to further grow the evidence base for the use of medicinal cannabis".

"We know the difference medicinal cannabis can make to people's lives," Ms Hennessy said. "That's why we're doing everything we can to help families legally access this treatment securely and safely."

The Victoria Government said it had provided funding to Austin Health for the trial.

The Government said that separate to the trial, it introduced new laws into the Victoria Parliament in December 2105 to allow families access to medicinal cannabis in exceptional circumstances.

The media release said that the Access to Medicinal Cannabis Bill 2015 was "an Australian-first" piece of legislation that will implement the Victorian Law Reform Commission Report of Medicinal Cannabis, establishing a legal framework for the cultivation, manufacturing, supply, patient eligibility and support on-going research in the field.

The legislation will be debated in the Lower House when Parliament resumes next week, the Government said.

LIVING CELL TECHNOLOGIES

Living Cell says it has ethics approval for its 18-patient, phase IIb clinical trial of NTCell pig brain cells for Parkinson's disease, expected to begin on February 24, 2016.

Living Cell said that the New Zealand Minister of Health authorized the trial application last year and today said that the Northern A Health and Disability ethics committee had approved the trial (BD: Nov 12, 2015).

The company said the four patient phase I/IIa trial "showed excellent safety data and clinically and statistically significant efficacy data in patients with Parkinson's disease one year after NTCell treatment" (BD: Jun 15, 2015).

Living Cell said that the phase IIb trial aimed to confirm the most effective dose of NTCell, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub group.

The company said that if the trial was successful it would apply for provisional consent and launch NTCell as the first disease-modifying treatment for Parkinson's disease in 2017.

Living Cell was up 0.3 cents or 5.8 percent to 5.5 cents.

ONCOSIL MEDICAL

Oncosil says it has raised $10 million in a placement at 22 cents a share “to drive commercialization of … [its] localised radiation treatment for cancer”.

Oncosil chief executive officer Daniel Kenny told Biotech Daily that the raising at 22 cents a share when the previous close was 22.5 cents a share reflected the confidence in the company’s program.

The company said that Bell Potter Securities was the placement lead manager and Biotech Daily believes that the capital raising was to a single institutional investor.

Mr Kenny said that the $10 million, along with $5.8 million that the company held at December 31, 2015, would go “a long way” to fund the pivotal trial, but he could not know how much it would cost until the US Food and Drug Administration had made a final decision on the trial design.

“The placement was about extending our runway and to be aggressive in our regulatory, clinical, manufacturing and commercials plans, and will take us well into 2018,” Mr Kenny said.

Mr Kenny said that the company had been transformed over the past 12 months.

“We have created a great management team, including the recent appointments of Cochlear’s Dr Chris Roberts as a director, as well as Tom Milicevic as chief financial officer,” Mr Kenny said.

Mr Kenny said Oncosil’s management team included former Sirtex executives Nicole Wilson as head of regulatory affairs and David James as head of manufacturing operations, as well as former Astrazeneca medical director Dr Ashish Soman as chief medical officer, with Charles Rowlands appointed to lead the US operations and with Dr Michelle Bradney as the head of medical affairs.

In a media release, Oncosil said that the brachytherapy technology was a new medical radiation treatment for pancreatic cancer and other solid tumors.

The company said that it had an investigational device exemption filing in progress with the US Food and Drug Administration and was concurrently pursuing Conformité Européenne (CE) mark certification.

In 2013, Oncosil (then Neurodiscovery) raised $1.5 million to acquire Psivida’s Brachysil technology invented by Dr Roger Aston and said it intended to begin a phase III trial in 2013, later raising $9 million in a placement and share plan, but the trial has not begun (BD: Feb 7, Sep 13, 2013).

In 2014, Oncosil said it had submitted its application for ethics approval to begin its 150-patient, randomized, controlled, pivotal trial for its localized radiation therapy for pancreatic cancer, with trial sites in Australia, the UK, Belgium, Singapore and later the US and said it was finalizing preparations for its US FDA investigational device exemption submission (BD: Mar 17, 2014).

Oncosil appointed Dr Neil Frazer as chief executive officer in July 2013, but in September 2014, he was moved to chief medical officer with Dr Roger Aston replacing chairman Martin Rogers and taking an executive role until Daniel Kenny was appointed as chief executive officer later that year (BD: Jul 3, 2013, Sep 9, Nov 11, 2014).

Scientia Capital’s Lawrence Gozlan was appointed a director in 2014 and resigned in 2015 (BD: Feb 27, 2014; May 4, 2015).

The current board is chairman Dr Roger Aston, Martin Rogers, Mr Kenny and the recently appointed former Cochlear chief executive officer Dr Chris Roberts.

Last year, Oncosil revised its trial design in February and filed the investigational device exemption to the FDA in December (BD: Feb 25, Dec 14, 2015).

Oncosil closed unchanged at 22.5 cents with 4.9 million shares traded.

ADMEDUS

Admedus says it has made its first sales of its Cardiocel cardiac repair scaffold in the Middle East and North African region through an early access program in Qatar.
Admedus said it expected additional sales of Cardiocel, which was used for the repair and reconstruction of cardiovascular defects, including reconstructing heart valves, in the region in the near future, with Genpharm as its exclusive partner for Cardiocel.
Admedus chief executive officer Lee rodne said that the first sale was “a positive step in the continued global launch of Cardiocel and adds to growing revenue for Admedus”.
“This first use of Cardiocel in Qatar is particularly important, as the … region is one of the fastest growing healthcare areas worldwide,” Mr Rodne said.
Admedus was up 2.5 cents or four percent to 64.5 cents.

DORSAVI

Dorsavi says the UK’s Jaguar Land Rover and Toyota have signed up for its Visafe wearable workplace assessments monitor systems.
Dorsavi did not disclose the value of the contracts.
The company said that the global automotive industry employed nine million people and it had identified the automotive and heavy vehicle manufacturing sectors as priority markets with large manual handling workforces and an interest in innovation to improve workplace safety and productivity.
Dorsavi said that along with contracts with the US-based Caterpillar company and Toyota Australia, the contracts with Toyota UK and Jaguar Land Rover broaden its expertise in transport and manufacturing.
The company said the car makers wanted it to help assess injury risk associated with specific tasks and to validate techniques to decrease the potential for workplace injuries.
Dorsavi fell one cent or 2.8 percent to 35 cents.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG has relisted on the ASX following its change of name and activities from Progen closing at 26.5 cents a 26.2 percent premium above its recent capital raising price.
Chairman Jitto Arulampalam told Biotech Daily that the company had raised $12.5 million at 21 cents and he was very pleased with the market response.
Last year, the then Progen said it would acquire TBG Inc from Taiwan’s Medigen Biotechnology Corp for 101,722,974 new shares and raise up to $14.5 million at 21 cents a share.
Progen said at that time that TBG was founded by Medigen in 2006, was incorporated in the Cayman Islands and had three wholly-owned subsidiaries, Texas Biogene, TBG Biotechnology Corp and TBG Biotechnology Xiamen, based in the US, Taiwan and China respectively.
The company said that TBG had research and development, manufacturing and sales operations and was “one of the leading providers of quality human leukocyte antigen typing kits for immune matching of bone marrow, cord blood and solid organ transplants”.
In May, Progen said that Medigen held 19.7 percent of the company and following completion Medigen would hold 64.8 percent of Progen (BD: May 1, 2015).
Progen closed a phase III trial of PI-88 for liver cancer in July 2008, sparking a fight for control over the company’s cash reserves and concluding with the drug being licenced to Medigen (BD: Jul 23, 2008; Apr 30, 2010).
TBG climbed four cents or 17.8 percent to 26.5 cents.

ALCHEMIA

Allan Gray Australia says it has ceased its substantial holding in Alchemia with the sale of 15,582,702 shares for $1,542,688 or 9.9 cents a share.
In November, Allan Gray said it held 29,529,489 shares or 9.09% percent, implying that it retained 13,946,787 shares or 4.29 percent (BD: Nov 16, 2015).
In June 2015, following the failure of Alchemia's phase III hyaluronic acid irinotecan trial for metastatic colorectal cancer, Allan Gray increased its holding to 56,755,167 shares but was diluted to 17.48 percent (BD: Oct 27, 2014; Jun 26, 2015).
Allan Gray said at that time that between May 31, 2007 and June 23, 2015 it bought and sold large numbers of shares at a range of prices, including through capital raisings in 2009, 2011 and 2013, as well as disposals through the ceasing of association with shareholders.
Alchemia was up, ex-9.3 cents capital return, 0.1 cents or 14.3 percent to 0.8 cents with 3.2 million shares traded.

ALCHEMIA

The Sydney-based Sandon Capital says it has increased its substantial holding in Alchemia from 59,159,180 shares (18.2%) to 64,619,996 shares (19.9%).
Sandon said it bought the 5,460,816 shares on-market, on February 1, 2016, following the shares going ex-capital return, for $46,022 or an average price of 0.84 cents a share.
Alchemia is in the process of paying 9.3 cents per share in a return of capital.

AGENIX

Agenix says that Adam Gallagher has been appointed as company secretary, replacing Gary Taylor, effective from February 2, 2016.
Agenix said that Mr Gallagher was appointed as a director in June 2015.
The company said that Mr Taylor was appointed company secretary in March 2011 and would continue as chief financial officer.
Agenix fell 0.1 cents or 7.1 percent to 1.3 cents with 73 shares traded.