Biotech Daily

Monday August 31, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 11.5%, IDT DOWN 13%**

*** BIONOMICS TO START US BNC101 COLON, PANCREATIC CANCER TRIALS**

*** MMJ, SATISPHARM SELL 1st MARIJUANA CAPSULES, AVAILABLE ON-LINE**

*** US DISASTER PREPAREDNESS AGENCIES INTEREST IN AVITA RECELL**

*** MEDICAL AUSTRALIA REVENUE UP 25% TO $15m, PROFIT TO $217k LOSS**

*** CLINUVEL REVENUE UP 29% to $3.3m, LOSS UP 89% TO $10.4m**

*** CELLMID REVENUE DOWN 16% to $3m, LOSS UP 126% TO $3.3m**

*** IMMURON REVENUE UP 7% to $1.1m, LOSS UP 36% TO $3.4m**

*** IQ3 REVENUE UP 2013% TO $922k, LOSS UP 96% TO $1.9m**

*** IM MEDICAL SURPRISED BY $270k LEGAL BILL**

*** NOVOGEN ADVISORY COMMITTEE SETS PIPELINE PRIORITIES**

*** ADHERIUM FOUNDER, CEO GARTH SUTHERLAND TAKES 8%**

*** MEDIBIO REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CHRIS SMITH TAKES COCHLEAR'S WHEEL, GOODBYE DR CHRIS ROBERTS**

MARKET REPORT

The Australian stock market fell 1.08 percent on Monday August 31, 2015 with the ASX200 down 56.6 points to 5,207.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and one was untraded.

Prana was best, up 1.5 cents or 11.5 percent to 14.5 cents with 148,761 shares traded. Avita and Optiscan climbed more than six percent; Reva was up 5.7 percent; Anteo and Psivida rose more than four percent; Medical Developments was up 3.9 percent; Antisense was up 2.5 percent; with Acrux, Ellex and Resmed up more than one percent.

IDT led the falls, down four cents or 13.3 percent to 26 cents with 153,249 shares traded. Atcor lost 9.5 percent; Actinogen fell 8.8 percent; Orthocell and Osprey fell more than six percent; Cellmid was down 5.9 percent; Admedus, Impedimed and Mesoblast fell more than four percent; Nanosonics and Neuren were down more than three percent; Bionomics and Pharmaxis shed more than two percent; with Benitec, Clinuvel and Universal Biosensors down more than one percent.

BIONOMICS

Bionomics says its BNC101 investigational new drug application (IND) submission to the US Food and Drug Administration has been accepted.

Bionomics said it planned to begin a phase I trial in patients with metastatic colon cancer and in patients with metastatic pancreatic cancer by December 31, 2015.

Bionomics chief executive officer Dr Deborah Rathjen said that the FDA acceptance was "a significant milestone for the company".

"BNC101 is a new class of anti-cancer agent which targets cancer stem cells," Dr Rathjen said.

"Many current drugs do not specifically target cancer stem cells," Dr Rathjen said.

"We believe that drugs, such as BNC101, specifically targeting cancer stem cells will reduce the risk of cancer recurrence and metastasis and have the potential to lead to better patient outcomes," Dr Rathjen said.

Bionomics said that BNC101 was a first-in-class, high affinity anti-LGR5 humanized monoclonal antibody targeting cancer stem cells.

The company said that the LGR5 receptor was over-expressed in metastatic colorectal cancer, metastatic pancreatic cancer and many other solid tumors.

Bionomics chief medical officer Dr José Iglesias said that BNC101 was discovered using the company's cancer stem cell recipe (CSCRx) platform and it was "immensely satisfying to see it move to this next stage of development".

In 2012, Bionomics said it had acquired BNC101 with Biogen Idec spin-out Eclipse Therapeutics and its CSCRx platform (BD: Sep 17, 2012).

"We are very encouraged by the results of our preclinical studies of BNC101 which have demonstrated efficacy in models of colon, pancreatic, breast and small cell lung cancer," Dr Iglesias said.

Bionomics said that BNC101 was designed to prevent or delay tumor recurrence and reduce cancer stem cells as a single agent and in combination with standard chemotherapy treatment and in preclinical studies BNC101 reduced circulating tumor cells that express LGR5.

Bionomics said that in IND-enabling preclinical studies BNC101 was well tolerated at doses up to 150mg/kg in a 28-day repeat dose study.

The company said the phase I trial would aim to demonstrate that BNC101 was safe and well-tolerated and able to delay disease relapse in patients treated for metastatic colorectal cancer and metastatic pancreatic cancer.

Bionomics said BNC101 would be trialled initially in combination with standard of care chemotherapies and later as a monotherapy to prevent or delay tumor relapse.

The company said that the market for metastatic colorectal cancer treatments was expected to grow to $US9.4 billion by 2020 and the US Center for Disease Control and Prevention estimated there would be about 133,000 new cases of metastatic colorectal cancer in the US in 2015.

Bionomics said the five-year survival rate for metastatic colorectal cancer patients was about 11 percent with a median overall survival span ranging from 20 to 30 months.

The company said that the pancreatic cancer drug market was estimated to be $US1.2 billion in 2015 with about 49,000 new cases of metastatic pancreatic cancer expected in the US this year.

Bionomics said that for pancreatic cancer patients overall, the five-year survival rate was about seven percent for all stages combined and two percent for patients with metastatic pancreatic cancer, with a median overall survival span for metastatic pancreatic cancer patients ranging from eight to 11 months.

Bionomics fell one cent or 2.4 percent to 40 cents.

MMJ PHYTOTECH

MMJ PhytoTech says its Swiss subsidiary Satipharm has sold its first cannabidiol capsules and it has launched a European Union online direct sales platform.
MMJ said that retail customers could buy its cannabidiol (CBD) capsules through its on-line website platform.
MMJ said that the Satipharm CBD Gelpell gastro-resistant microgel capsules consisted of pharmaceutical-grade CBD mono-compound and were registered as a dietary supplement in Germany.
The company said that the capsules were produced in partnership with Ai Fame GmbH and contract supplements manufacturer Gelpell AG and Phytopharmaka, both based in St Gallen, Switzerland.
MMJ said that the cannabidiol was derived from “a proprietary medicinal cannabis strain” grown in Switzerland under controlled standards and extracted by Ai Fame, under supervision of the Swiss Health Authorities.
The company said it intended to produce a total of 1,000,000 capsules in 2015, selling at about EUR3 ($A4.73) per capsule retail and EUR1.95 ($A3.07) wholesale.
MMJ said that the packs of 30 capsules were available in 10mg and 100mg blister packs for EUR89 ($A140.21) and EUR579 ($A912.18), respectively
The company said that biochemist and professional pharmaceutical representative Laura Boersen had been appointed head of international sales.
MMJ was up 6.5 cents or 22.4 percent to 35.5 cents with 3.7 million shares traded.

AVITA MEDICAL

Avita says US Government agencies have given “a high rating to … [explore] the possible use of Recell under a disaster preparedness program.
Avita said that it had received a notification from the US Biomedical Advanced Research and Development Authority (BARDA) and the US Department of Health and Human Services Office of Acquisition Management, Contracts, and Grants had evaluated the company’s proposal and determined that it was “within the competitive range”.
Avita said the evaluation was a determination reserved for the most highly rated proposals.
The company said it would begin formal negotiations with BARDA on a range of technical and commercial issues.
Last week, Avita requested a trading halt and later a voluntary suspension while it completed an “equity placement” (BD: Aug 26, 28, 2015).
Today, Avita said that it considered it “prudent to ensure that the market is aware of all information prior to proceeding with the capital raising” and requested that the suspension of trading be lifted.
Avita chief executive officer Adam Kelliher said the company welcomed the US agencies response and would engage with BARDA to address their requests for further specific information.
The company said that BARDA was seeking to fund late-stage development and procurement of autograft-sparing products that could enhance the capacity to provide definitive care for thermal burn injuries.
Avita said that BARDA used a competitive bidding process and the awarding of, or timing for, a contract was uncertain and if it did receive an award, there were no certainties that it would be able to satisfy of the conditions of the award.
Avita was up half a cent or 6.9 percent to 7.7 cents.

MEDICAL AUSTRALIA

Medical Australia says that revenue for the 12 months to June 30, 2014 was up 25.1 percent to $14,856,014 turning last year's profit to a $216,879 net loss after tax.
Medical Australia said the increased revenue was partly due to 12 months of animal health revenue compared to seven months in the year to June 30, 2014, but the majority came from human healthcare which was up 15 percent for the year to June 30, 2015.
The company said net tangible assets per share fell 13.7 percent to 3.16 cents with diluted loss per share of 0.175 cents compared to the previous year's earnings of 0.14 cents a share and it had cash and cash equivalents of $933,312 at June 30, 2015, compared to $1,757,258 at June 30, 2014.
Medical Australia was untraded at 6.5 cents.

CLINUVEL

Clinuvel says revenue for the year to June 30, 2015, was up 29.0 percent to $3,259,962 with net loss after tax up 88.5 percent to $10,414,376.
Clinuvel said that revenue from Scenesse for erythropoietic protoporphyria sales in Italy and Switzerland under special access schemes increased 32.4 percent to $2,912,000.
The company said diluted loss per share was up 67.8 percent to 24.0 cents at June 30, 2015 and net tangible assets per share fell 30.6 percent to 25 cents, with $10,572,295 in cash and cash equivalents at June 30, 2015, compared to $14,625,583 at June 30, 2013.
Clinuvel fell three cents or one percent to $2.91.

CELLMID

Cellmid says revenue for the year to June 30, 2015, fell 16.4 percent to $2,967,562 with net loss after tax up 126.4 percent to $3,337,348.
Cellmid said that revenue from the sale of goods, primarily its Advangen hair loss products was up 60.1 percent to $1,842,804.
The company said that last year it reported revenue of $2,795,948 which did not include the Federal R&D Tax Incentive and one-off licence income, but new accounting standards required reporting that revenue.
Cellmid said that diluted loss per share was up 104.8 percent to 0.43 cents at June 30, 2015 and net tangible assets per share was up 52.9 percent to 0.24 cents.
Cellmid said it had $1,582,899 in cash and cash equivalents at June 30, 2015, compared to $2,501,753 at June 30, 2013.
Cellmid fell 0.2 cents 5.9 percent to 3.2 cents with 4.15 million shares traded.

IMMURON

Immuron says revenue for the year to June 30, 2015, was up 7.6 percent to $1,123,707 with net loss after tax up 35.5 percent to $3,447,951.
Immuron said that sales of the travellers' diarrhoea preventative product Travelan had increased.
The company said that diluted loss per share was up 29.7 percent to 4.407 cents at June 30, 2015 and net tangible assets per share fell 33.0 percent from 9.062 cents at June 30, 2014 to 6.068 cents at June 30, 2015.
Immuron said it had $3,116,074 in cash and cash equivalents at June 30, 2015, compared to $6,141,789 at June 30, 2014.
Immuron fell half a cent or 1.2 percent to 41.5 cents.

IQ3

IQ3 says that revenue for the 12 months to June 30, 2015 was up 2013.4 percent to $922,211 with net loss after tax up 95.8 to $1,910,855.
IQ3 said that all of its income came from consulting fees.
The company said that net tangible assets per share fell 73.2 percent to 3.77 cents at June 30, 2015, compared to 14.08 cents at June 30, 2014 with diluted loss per share up 89.3 percent to 2.31 cents.
IQ3 said it had cash and cash equivalents of $3,846,198 at June 30, 2015, compared to $685,548 at June 30, 2014.
IQ3 was up three cents or 10.7 percent to 31 cents.

IM MEDICAL

IM Medical says it has received a claim for $269,766 for legal costs relating to a proposed capital raising for the failed acquisition of White Data (BD: Aug 26, 2014).
IM Medical said that the acquisition and capital raising did not proceed and legal work on the capital raising ceased in February 2014.
The company said it previously had not received any invoices for the legal costs for the period from September 2013 to February 2014, which totalled $269,766 excluding GST.
IM Medical said it was reviewing the invoices.
IM Medical last traded at 0.1 cents.

NOVOGEN

Novogen says a scientific review committee has determined its priorities following the departure of founder and former executive chairman Dr Graham Kelly.
Novogen acting chief executive officer Iain Ross said that a scientific review committee was created with members including former Eli Lilly & Co Bryce Carmine, the University of New South Wales Prof Peter Gunning and the new Haven Connecticut-based Yale University's Prof Gil Mor.
The company's website said that Mr Carmine and Prof Gunning were Novogen directors and the company previously reported work on Trx-1 for ovarian cancer by Prof Mor through the Novogen-Yale joint venture company Cantx (BD: Mar 18, 2014).
Today, Mr Ross said that the committee had "identified realistic opportunities based on the extensive data available for our lead drug candidates".
"Pending … required safety studies we are committed to progressing Cantrixil and Anisina to phase I clinical trials in 2016 and Trilexium by 2017," Mr Ross said.
Mr Ross said the company would pursue a patent protection approach for its degenerative and regenerative medicine program known as Jacob's Hope, which would "take a lower profile while we focus on the nearer term core opportunities".
Novogen said that it "continues to target 2016" to begin a first-in-human safety trial of Cantrixil for ovarian cancer in Australia.
Novogen said it was committed to paediatric neuroblastoma and had medical experts to participate on an Anisina paediatric oncology board.
The company said that it had "identified a high value opportunity where there are currently no approved treatments and the current life-expectancy for patients is no more than eight months" for Trilexium, or TRXE-009 and expected to begin first-in-human trials for diffuse intrinsic pontine glioma by 2017 and planned to file for orphan drug designation status with the US Food and Drug Administration.
Novogen was unchanged at 15 cents with 1.6 million shares traded.

ADHERIUM

Adherium founder, chief executive officer and chief technology officer Garth Sutherland has become substantial in his company with 11,174,450 shares (7.98%).
The Auckland, New Zealand-based Mr Sutherland said that shares were acquired under a share swap agreement.
Adherium fell three cents or 4.35 percent to 66 cents.

MEDIBIO (FORMERLY BIOPROSPECT)

Medibio has requested a trading halt “pending the announcement of the completion of a capital raising”.
Trading will resume on September 2, 2015 or on an earlier announcement.
Medibio last traded at 46.5 cents.

COCHLEAR

Cochlear says that Christopher Michael Smith’s appointment as chief executive officer and as an executive director is effective from tomorrow, September 1, 2015.
Cochlear said that Dr Christopher Graham Roberts would step down as chief executive officer and cease to be a director of Cochlear
Biotech Daily wishes Dr Roberts all the best for the future and hopes to report on his next great leap forward.
Cochlear was up 35 cents or 0.4 percent to $85.43 with 422,289 shares traded.