

# **Biotech Daily**

# Thursday October 13, 2011

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: ANTISENSE UP 12.5%; CELLMID DOWN 13%
- \* GBS 1998 IIF \$42.5m INVESTMENT BEATS US PEERS
- \* EUROPE APPROVES ACRUX RECUVYRA PAIN RELIEF FOR DOGS
- \* AVITA LAUNCHES RECELL FOR VENOUS ULCERS IN EUROPE
- \* AGENIX SIGNS CHINA DEALS FOR AGX-1009 FOR HEPATITIS B
- \* AMP REDUCES BELOW 5% IN SIRTEX
- \* CBIO RAISES \$7.3m OF UNDERWRITTEN \$10.8m
- \* CBIO CHAIR STEPHEN JONES, 2 DIRECTORS LOSE EXECUTIVE ROLES
- \* ATCOR WINS US MEDICARE REBATE APPEAL
- \* JDJ DISTRIBUTES CHARLES RIVER CRO SERVICES
- \* HELICON REQUESTS ASPEN MEDISYS TRADING HALT

## MARKET REPORT

The Australian stock market climbed 0.96 percent on Thursday October 13, 2011 with the S&P ASX 200 up 40.2 points to 4,244.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and 10 were untraded.

Antisense was the best, up 0.1 cents or 12.5 percent to 0.9 cents with 530,000 shares traded.

Living Cell climbed 7.1 percent; Phosphagenics was up 6.25 percent; Sirtex and Sunshine Heart were up more than four percent; Nanosonics and Phylogica were up more than three percent; Cochlear and Tissue Therapies rose more than two percent; with Acrux, Anteo, Biota and Starpharma up more than one percent.

Cellmid led the falls, down 0.3 cents or 13 percent to two cents with 18.8 million shares traded, followed by Prana down 11.1 percent to 16 cents with 7,600 shares traded.

Alchemia lost 9.1 percent; Reva fell 4.9 percent; Bionomics and Genetic Technologies were down more than three percent; QRX shed 2.65 percent; with Viralytics down one percent.

## **GBS VENTURES**

GBS Ventures says its 1998 vintage life science venture capital fund has out-performed the top quartile performance of US life sciences venture capital finds.

GBS managing director Dr Brigitte Smith told Biotech Daily that according to data from Cambridge Associates the upper quartile of US funds returned 1.49 times their 1998 collective investment and the \$42.5 million invested by GBS in its Australian Bioscience Trust out-performed its US peers.

Dr Smith said GBS would not disclose how much the fund returned.

"Australian superannuation funds invest in US venture funds and are reluctant to invest in Australian venture funds," Dr Smith said.

"But we are as good as the top quartile of US venture funds," she said.

Dr Smith said the comparison was based on fully-realized cash-on-cash returns net of fees.

In a media release, GBS said the fund delivered investors a premium to the all ordinaries accumulation index, and small ordinaries accumulation index over the period.

"This result vindicates our strategy of building world class Australian life science companies to create superior returns for our investors," Dr Smith said.

GBS said that the Australian Bioscience Trust helped build Australian life sciences success stories such as Pharmaxis, Alchemia and Cogstate, all of which were now public companies, delivering products to treat cystic fibrosis and asthma, to help prevent blood clots, and to diagnose central nervous system diseases.

Pharmaxis chief executive officer Dr Alan Robertson said that GBS "provided our founding capital and helped guide us through the highs and lows of biotech product development". "Without GBS, our products to treat global respiratory diseases would not have been developed," Dr Robertson said.

GBS said that the Australian Bioscience Trust invested in 11 companies and made the final realizations in the past three months, with a sale to Wolfson Microelectronics of Dynamic Hearing.

GBS said Dynamic Hearing was a leading provider of audio digital signal processing technology for personal communication devices such as mobile phones, Bluetooth headsets and hearing aids.

GBS said the fund was raised under the Australian Government's Innovation Investment Fund, a venture capital program supporting innovation funds and fund managers with expertise in early-stage venture capital investing.

GBS said that the Government's Innovation Investment Fund co-invested with private sector investors in venture capital funds to assist early-stage companies to commercialize the outcomes of Australia's strong research capability.

GBS said that since 1998 it had actively invested in Australian biotechnology, raised three subsequent funds entirely from private sector investors and had more than \$400 million under management and its investors include major Australian superannuation funds. The firm said it was seeking new lifescience investment opportunities for its 2008 vintage \$122.5 million GBS Bioventures IV.

GBS managing director Dr Geoff Brooke said that the IIF program "gave us our start in the venture capital industry and we believe that we have achieved all of the program objectives".

"These results demonstrate GBS can build Australian life science companies that export into major global markets, create high value jobs and create products to treat major diseases, and ultimately deliver sustainable returns to our investors," Dr Brooke said. GBS is a private company.

## <u>ACRUX</u>

Acrux will receive a \$500,000 payment following European marketing authorization for the commercial use of Recuvyra 50mg/mL transdermal fentanyl for dogs.

Acrux said Recuvyra was approved by the European Medicines Agency for the control of post-operative pain associated with major orthopedic and soft tissue surgery in dogs.

The company said a single dose applied to the skin of dogs prior to surgery controlled pain for at least four days.

Acrux said the product was developed using a transdermal drug delivery technology licenced from Acrux to Eli Lilly's Elanco division and as well as the \$500,000 milestone payment following approval, it would also earn royalties on sales.

The company said the marketing authorization was the first approval of Acrux's transdermal technology in animal health.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily that the company was "delighted that the first veterinary product had been approved".

"It underpins a very productive relationship with Eli Lilly," Dr Treagus said.

Dr Treagus said Eli Lilly was investigating Recuvyra for use in other animals and it was originally licenced in 2004 for potential use in dogs, cats and horses.

Dr Treagus said a US Food and Drug Administration marketing decision was expected "in the next few months" and the company hoped to have product launches in Europe early in 2012 and in the US in mid 2012.

Acrux was up six cents or 1.7 percent to \$3.58.

## AVITA MEDICAL

Avita Medical has launched its Recell spray-on skin for the treatment of chronic leg ulcers, in Europe, a market estimated at more than \$1 billion.

Avita's Asia-Pacific general manager Lorraine Glover told Biotech Daily that Recell had approval as a device to harvest cells for wound treatment and could be used for the new indication of venous ulcers.

In a media release, Avita said data on the use of Recell to treat chronic ulcers in 10 patients was presented at the International Flebology Conference in Ferrara, Italy, September 29 to October 1, 2011.

The company said one patient was lost to follow-up due to an unrelated accident and of the remaining nine patients, 100 percent healing was achieved in eight patients with approximately 90 percent re-epithelialization achieved in the remaining patient.

The data was presented by the Arezzo-based San Giuseppe Hospital's Dr Giuliano Magi in an address entitled 'Autologous transplantation of epidermal cells in difficult to treat ulcers of the lower limbs'.

Avita said the patients' ulcers had been treated during the preceding 24 months with the standard of care including compression therapy alone or in combination with skin grafts. The company said that depth, area, volume and extent of ulcers prior to and post-treatment with Recell were objectively quantified using a 3D laser scanner.

Dr Magi said that Recell "demonstrated a very high success rate in the treatment of chronic leg ulcers".

"Although we have only a limited sample size, the outcomes in these recalcitrant ulcers are clinically outstanding and cost-effective for the healthcare system," Dr Magi said. "Furthermore patients report an immediate decrease in pain and are resuming normal activities straight after the Recell procedure making it more acceptable to the patients themselves," Dr Magi said.

Avita was up 1.1 cents or 11.1 percent to 11 cents with 1.3 million shares traded.

## <u>AGENIX</u>

Agenix says it will commercialize drug candidates, share resources, expertise and complete pre-clinical toxicology tests with its Chinese partners for a hepatitis B drug. Agenix says China's Institute of Pharmacology and Toxicology of the Academy of Military Medical Sciences would complete final toxicology tests for the hepatitis B compound AGX-1009 ahead of the expected start of clinical trials in China in 2012.

Agenix said an agreement with strategic partner, the Institute of Medicinal Biotechnology of the Chinese Academy of Medical Sciences in Beijing covered development of drug candidates, shared intellectual property, production, marketing, distribution and access to the Institute's research and regulatory expertise.

Agenix chairman and chief executive officer Nicholas Weston said the agreements reinforced "our commercial position in China and is another step towards the creation of long-term shareholder value by developing new drugs to address large unmet clinical needs".

Agenix said the Institute of Medicinal Biotechnology was an internationally respected organization that has played a major role in the development of several important new drugs and collaborated with the Bill and Melinda Gates Foundation, Vertex Pharmaceuticals and Bethesda Hospital Maryland.

The company said that AGX-1009, shares the same active compound as Gilead's Viread which was used to treat HIV and hepatitis B and was supported by the Chinese Government's State Special Funds for Important Newly-Developed Drugs to develop cost effective medicines for large unmet medical needs in China.

Agenix was up 0.2 cents or 13.3 percent to 1.7 cents with 3.3 million shares traded.

## SIRTEX MEDICAL

The Sydney-based AMP Capital Investors has ceased its substantial shareholder in Sirtex reducing below five percent of the company.

The AMP notice said it bought and sold shares between September 5 and October 12, 2011, with the single largest transaction the sale of 1,789,698 shares for \$8,052,312 or \$4.50 a share.

In August AMP said it became substantial in Sirtex with the acquisition of 2,875,398 shares or 5.16 percent of the company (BD: Aug 12, 2011).

The August substantial shareholder notice said the AMP acquired the shares for Cogent Nominees between April 19 and August 11, 2011, with the most recent purchase, the largest with 801,795 shares bought for \$4,178,507 or \$5.21 a share. Sirtex was up 20 cents or 4.3 percent to \$4.90.

## <u>CBIO</u>

CBio says it has raised \$7.26 million of its underwritten maximum \$10.8 million shareholder three-for-eight rights issue and 18 cents a share.

CBio said that of the \$7.26 million raised, it received applications for \$5.67 million, with \$1.59 million in additional and shortfall applications.

The company said the offer was underwritten by Zheng He Securities.

CBio said it would place the 28,530,617 shortfall shares totaling \$5.14 million in

accordance with the underwriting agreement and expected all remaining shortfall shares to be issued during October.

CBio fell half a cent or 1.8 percent to 27 cents.

# <u>CBIO</u>

CBio says chairman Stephen Jones, managing director Jason Yeates and finance director James Greig will resign from their executive roles but remain as non-executive directors. In a media release entitled 'CBio board and executive changes' the company said that Mr Jones, Mr Yeates and Mr Greig had stepped down from their executive roles but would remain on the board as non-executive chairman and non-executive directors, respectively. Last month, the CBio shareholder action group called for a general meeting to replace Mr Jones and directors Prof John Funder and James Greig to be replaced by former Amrad director and Avexa chair Helen Cameron, Dr Ralph Craven and Warren Brown. (BD: Sep 5, 7, 2011).

The meeting will be held on November 4, 2011 (BD: Sep 26, 2011).

Today, CBio said that Mr Jones was the founding chairman and held the position of executive chairman since 2006 and Mr Jones and Mr Yeates would continue to manage the company's relationship with Novo Nordisk and other pharmaceutical companies in their capacity as non-executive directors.

CBio said the head of clinical development Dr Daina Vanags had been appointed chief operating officer and would oversee the clinical and scientific direction of the company. The company said that Dr Vanags joined CBio in 2004 and was experienced in pre-clinical and clinical trial design, scientific development and regulatory development.

CBio said that company secretary Ben Graham had been appointed chief financial officer, had been the financial accountant since 2005 and company secretary since 2007 and would step down as company secretary in the near future.

Mr Jones said the timing was "certainly right to make these changes".

"The clinical trial [of XToll for rheumatoid arthritis] is now complete and we are in the process of finalizing the study report, which will be delivered to Novo Nordisk as well as other pharma companies in the near future," Mr Jones said.

The phase II trial showed that XToll did not meet its primary endpoint (BD: Aug 1, 2011). The shareholders' action group supports the drug but says the that missing the primary endpoint was the result of under-dosing (BD: Sep 7, 2011).

## ATCOR MEDICAL

Atcor says the US Office of Medicare Hearings and Appeals has found that the New York State Medicare contractor must reimburse Sphygmocor tests on Medicare patients. Atcor said that in making the rulings on three cases, the appeal judge focused on the medical value of the information Sphygmocor testing provided, stating in one decision summary: "[The] beneficiary has a history of past hypertension, dyslipedemia and anticardiolipin syndrome, as well as thoracic aortic aneurysm".

"Her physician was concerned about control of central pressure to determine if he should proceed aggressively or not," the judge was reported saying. "He chose not to proceed any further knowing the patient's central aortic pressure was adequately controlled; which he learned from this procedure," Atcor reported the judge saying.

Atcor chief executive officer Duncan Ross said the company was "very pleased with the New York rulings, which are consistent with similar favorable decisions on care provided to Medicare patients in the multi-state Michigan Medicare region".

"In every case brought before the Office of Medicare Hearings and Appeals to date, judges have found that Sphygmocor testing satisfied the criteria for Medicare coverage and reimbursement," Mr Ross said.

Atcor's Sphygmocor system non-invasively measures central blood pressure. Atcor was unchanged at seven cents.

## JDJ BIOSERVICES

The Richmond, Melbourne-based JDJ Bioservices says it will be the Australian and New Zealand representative for Charles River Biopharmaceutical Services.

A JDJ Bioservices media release said that Charles River provided testing and manufacturing of biologics to accelerate drug development.

JDJ said that the assays provided ranged from cell characterization and process validation studies to stability and product release testing, while manufacturing services included cell banking, storage, fill and finish, as well as viral vaccine and antisera production.

JDJ chief executive officer Dr Julian Chick said Charles River was "one of the world's foremost R&D contract research organisations, in the biologics area".

JDJ is a private company.

## HELICON GROUP

Helicon has requested a trading halt "pending an announcement in relation to the proposed acquisition of Aspen Medisys".

In May, Helicon said Aspen owned a nanoparticle technology for the treatment of tumors codeveloped with Aduro Biotech Inc, a significant shareholder in Aspen (BD: May 4, 2011).

Trading will resume on October 17, 2011 or on an earlier announcement. Helicon last traded at two cents.