Biotech Daily

Thursday August 25, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN:**
- SUNSHINE HEART UP 20%, ANTISENSE DOWN 12.5%

*** SIRTEX REVENUE UP 1.2% TO $73m, PROFIT DOWN 29% TO $11.5m**

*** GENETIC TECHNOLOGIES MAIDEN PROFIT; REVENUE UP 111% TO $18m**

*** FDA APPROVES AVITA RECELL SCAR TREATMENT TRIAL**

*** QRX FILES MOXDUO CLINICAL DATA PACK TO FDA**

*** GENETIC TECHNOLOGIES, ATTOMOL SETTLE PATENT ACTION**

*** QRX RIGHTS ISSUE RAISES $1.5 OF HOPED FOR $10m**

*** IMMURON PLACES $517k**

*** COGSTATE CLAIMS $1m DEPRESSION TRIAL CONTRACT**

*** CBIO, SPRINGTREE TERMINATE DRAW DOWN EQUITY LOAN**

MARKET REPORT

The Australian stock market climbed 1.08 percent on Thursday August 25, 2011 with the S&P ASX 200 up 45.2 points to 4212.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and nine were untraded.

Sunshine Heart was the best, up 0.8 cents or 20 percent to 4.8 cents with 4.1 million shares traded, followed by Living Cell up 11.1 percent to six cents with 955,638 shares traded.

Optiscan climbed 9.4 percent; Genetic Technologies was up 6.45 percent; Cellmid rose five percent; Biota and Prana were up more than three percent; CSL rose 2.7 percent; with Impedimed, Mesoblast and Pharmaxis up one percent or more.

Antisense led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with three million shares traded.

Universal Biosensors lost 7.2 percent; Benitec fell four percent; Tissue Therapies was down 3.2 percent; Starpharma and Viralytics shed more than two percent; with Acrux, Alchemia, Anteo, Bionomics, Heartware, Nanosonics, Patrys and Sirtex down one percent or more.

SIRTEX MEDICAL

Sirtex says revenue for the 12 months to June 30, 2011 was up 1.2 percent to $72,954,000 with net profit after tax down 28.6 percent to $11,479,000.
Sirtex said dose sales of the Sir-Spheres treatment for liver cancer were up 19 percent for the 12 months to 4,977 doses, with product revenue up nine percent to $70.3 million.
The company said a fully-franked final dividend of seven cents per share would be paid.
A spokesman for Sirtex told Biotech Daily the fall in profit was due to reinvestment in clinical support and sales staff, primarily in the US, along with expenditure on a manufacturing facility in Singapore.
Sirtex chief executive officer Gilman Wong said the results reflected “a growing awareness and acceptance of SIR-Spheres microspheres as a treatment for inoperable liver cancer”.
“This is supported by the publication of the results of a number of recent independent clinical studies showing the benefits of SIR-Spheres microspheres adding to the already significant body of evidence,” Mr Wong said. “It is worth reflecting that the dose sales still represent less than one percent of the addressable global market of people diagnosed worldwide with liver cancer each year.”
“We are very confident this growth will continue as our business is now based on very solid foundations and we continue to invest in building the infrastructure to enable more significant growth in the future,” Mr Wong said.
Sirtex said cash at June 30, 2011 was up 3.6 percent to $42.9 million compared to the previous year.
The company said that diluted earnings per share fell 29.2 percent to20.4 cents compared to the previous year’s 28.8 cents.
Sirtex fell five cents or one percent to $5.15.

GENETIC TECHNOLOGIES

Genetic Technologies has reported a maiden net profit after tax for the 12 months to June 30, 2011 of $901,341 on revenue up 111 percent to $18,275,701.
Genetic Technologies said the revenue primarily came from $13,680,741 in licencing fees compared to the previous year’s $3,739,747, with a 6.5 percent fall in genetic testing services to $4,594,960.
The company said the maiden profit compared to a net loss after tax for the year to June 30, 2010 of $9,355,209.
Genetic Technologies reduced its expenditure on laboratory and research and development costs 30 percent to $4,380,866.
Genetic Technologies chief executive officer Dr Paul MacLeman said the increase in revenue and savings “from a strident cost reduction and containment program supported the delivery of the company’s maiden profit”
Dr MacLeman said the company “made significant progress during the period on our molecular diagnostics strategy, with the market preparation and US launch of the … breast cancer risk test Brevagen in June” (BD: Jun 20, 2011).
Dr MacLeman said the market for Brevagen in the US was about 1.1 million tests a year.
The company said diluted earnings per share was 0.22 cents compared to the previous year’s loss of 2.46 cents.
Genetic Technologies said it had $5,104,667 in cash and cash equivalents at June 30, 2011, compared to $3,306,311 at June 30, 2010, but after June 30, 2011 it raised $11.7 million, taking total cash reserves to more than $15 million at July 31, 2011.
The company said no dividend would be paid.
Genetic Technologies was up one cent or 6.45 percent to 16.5 cents.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved a feasibility study of its Recell wound treatment for hypertrophic dyspigmented scars.

Avita said hypertrophic dyspigmented scars were raised and/or discolored scars and 20 patients with pre-existing scars would be treated at up to four US study sites.

The company said that the treated scars would be assessed for healing and pain on a weekly basis during the initial four weeks post-treatment and at weeks 12 and 24 the treatment sites would be assessed for healing and aesthetic outcomes by both the patient and the surgeon.

Avita chief executive officer Dr William Dolphin said the company was pleased the FDA approved the investigational device exemption request to study expanded indications for the Recell Spray-On- Skin wound treatment.

“We believe that Recell offers the potential to deliver significant benefits over currently available options in the treatment of acute and chronic wounds and skin defects,” Dr Dolphin said.

“This study will allow us to demonstrate the use of Recell in the corrective treatment of existing scars with application to the very large cosmetic markets,” Dr Dolphin said.

Avita said the Recell scar feasibility study was primarily designed to assess the effectiveness of using Recell for the treatment of existing scars in a single treatment session, measured as time-to-healing and aesthetic outcomes, compared to the current standard of care which involved dermabrasion of the existing scar and often requires multiple sessions.

The company said that data obtained from the feasibility study would be used to design a larger, statistically-powered, pivotal clinical investigation.

Avita said that once the 12-week follow-up with the 20th patient was completed, the company would submit the feasibility data to the FDA and seek approval for the pivotal trial protocol.

Avita said it was currently conducting an FDA-approved study for the use of Recell in the treatment of acute burn wounds.

The Recell treatment was originally developed by the Royal Perth Hospital Burns Unit’s Prof Fiona Wood, who continues as a director of the company.

Avita was up half a cent or 4.35 percent to 12 cents.

QRX PHARMA

QRX says it has submitted its new drug application clinical data package to the US Food and Drug Administration for Moxduo immediate-release (IR).

QRX said the new drug application’s chemistry, manufacturing and controls module for the dual-opioid combination of morphine and oxycodone for pain was submitted last month and was under review (BD: Jul 18, 2011).

The company said submission of the clinical data from phase III clinical program completed its filing requirements and the FDA typically took 10-12 months to review applications.

QRX chief executive officer Dr John Holaday said the filing was a milestone and he looked forward to the regulatory approval process that could enable sales in 2012.

QRX said it had requested a priority review “based on favorable clinical data from several head-to-head comparisons with morphine, oxycodone, Percocet and placebo”.

The company said US filing would serve as the core component of Moxduo registration submissions in Europe, Australia, Canada and elsewhere.

QRX was up half a cent or 0.4 percent to $1.345.

GENETIC TECHNOLOGIES

Genetic Technologies says it has signed a settlement and licence agreement with Attomol GmbH relating to its non-coding DNA intellectual property.
Genetic Technologies said the Lipten, Germany-based Attomol was granted nonexclusive rights to a number of patents relating to the non-coding DNA technology, but the commercial terms of the agreement were confidential and could not be disclosed.
The company said that Attomol was not a counterparty to the other ongoing formal assertion cases filed in the US courts.
Genetic Technologies said that discussions with other parties were ongoing and progressing (BD: Feb 16, 2010; Apr 13, May 26, 2011).

QRX PHARMA

QRX says its non-renounceable one-for-20 rights issue at $1.45 a share has raised $1,517,208 from the issue of 1,046,351 shares.
QRX said there was a shortfall of 6,107,353 shares in the rights issue.
Last month, QRX placed $25 million of shares at the same price (BD: Jul 20, 2011).

IMMURON

Immuron says it has raised $516,600 through the issue of 7,380,000 shares at seven cents each to sophisticated and professional investors.
Immuron did not announce the placement but reported it an Appendix 3B new issue application to the ASX.
The shares come with one attaching option for every parcel of three new shares exercisable at 10 cents by August 31, 2012.
Earlier this month Immuron announced a non-renounceable one-for-five share rights issue at seven cents a share to raise up to $4,388,080 (BD: Aug 17, 2011).
Immuron said that participatns in the rights issue would receive one attaching option for every three new shares acquired, exercisable at 12 cents by December 15, 2013.
Immuron was untraded at 6.6 cents.

COGSTATE

Cogstate says it has signed a $1.05 million contract to assist an unnamed pharmaceutical company in a phase III clinical trial for the treatment of major depression.
Cogstate said the contract would generate $US1.1 million ($A1.05 million) in revenue for the provision of its cognitive testing technology and associated services to 600 patients in up to 75 sites around the world.
The company said its computerized cognition testing software and associated on-line site training materials would be provided in 15 languages.
Cogstate said that cognition measured by its tests would be a secondary endpoint.
The company said it was “the second large clinical trial for the treatment of major depressive disorder … signed in the last three months”.
Cogstate was untraded at 17 cents.

CBIO

CBio says the $12.45 million Springtree Special Opportunities Fund convertible loan agreement “has been terminated by mutual consent with immediate effect”.

CBio managing director Jason Yeates said the funding “provided a level of financial stability for the company over the past year during which time the company completed its phase IIa [rheumatoid arthritis] clinical trial” (BD: May 17, 2010).

“Completion of the clinical trial was a significant milestone for CBio and we thank Springtree for their valuable support over this important period,” Mr Yeates said.

Earlier this month CBio said the 155-patient phase IIa XToll trial failed to meet its primary endpoint, saying the 75mg dose was ‘sub-optimal’ (BD: Aug 1, 2011).

CBio was up one cent or 3.85 percent to 27 cents.