Biotech Daily

Thursday August 13, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: SIRTEX UP 10%, AVITA DOWN 6%**

*** SIRTEX RECORD REVENUE UP 36% to $178m, PROFIT UP 69% TO $40m**

*** NEUREN EU ORPHAN STATUS FOR TROFINETIDE FOR RETT, FRAGILE X**

*** ACRUX REVENUE, PROFIT DOWN – 12 GENERICS PIPELINE**

*** REVA FANTOM II TRIAL ON-TRACK, FUNDS SECURE**

*** GENETIC SIGNATURES SIGNS POLAND, IRELAND DISTRIBUTORS**

*** GORDAGEN HIRES ASCENDIANT AS US BANK, ADVISOR**

*** PERPETUAL BELOW 5% OF PRO MEDICUS, AGAIN**

*** OBJ GRANTS ADVISORS PROF WRIGHT, DR BENSON 2m SHARES**

*** DR THOMAS LÖNNGREN TALKS EU REGULATION AT BIO-MELBOURNE**

MARKET REPORT

The Australian stock market edged up 0.11 percent on Thursday August 13, 2015 with the ASX200 up 5.8 points to 5,387.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and three were untraded.

Sirtex was the best, up $2.91 or 9.7 percent to $32.94 with 1.3 million shares traded.

Acrux climbed 8.96 percent; Cellmid rose 6.1 percent; Antisense, Benitec and Prana were up more than three percent; Anteo, Osprey and Psivida rose more than two percent; Actinogen, Biotron, Nanosonics, Neuren and Starpharma were up more than one percent; with Impedimed up 0.4 percent.

Avita led the falls, down half a cent or 6.25 percent to 7.5 cents with 22,093 shares traded.

Clinuvel and Universal Biosensors fell four percent or more; Compumedics, Genetic Technologies and IDT were down more than three percent; Living Cell, Mesoblast, Optiscan, Orthocell, Pharmaxis and Prima shed two percent or more; Medical Developments, Tissue Therapies and Viralytics were down more than one percent; with CSL and Resmed down by less than one percent.

SIRTEX MEDICAL

Sirtex says that revenue for the 12 months to June 30, 2015 was up 35.6 percent to $177,977,000 with net profit after tax up 69.0 percent to $40,345,000.

Sirtex said that dose sales of its radioactive SIR-spheres for liver cancer increased 19.8 percent to a record 10,252 doses, with sales revenue up 36.1 percent to $176,088,000.

The company said there were increased dose sales in all regions with the Americas up by 21.2 percent to 7,076 doses; Europe, the Middle East and Africa up 18.6 percent to 2,273 doses; and Asia Pacific up 11.6 percent to 903 doses.

In a teleconference, Sirtex chief executive officer Gilman Wong said that the company's "2020 Vision" was built on the three pillars of expanding the use of SIR-Spheres for primary and secondary liver cancer to kidney and other cancers as well as expanding research and development and mergers and acquisitions activity.

Mr Wong said the carbon cage collaboration with the Australian National University was to deliver substances to specific cancer sites deep within the body as well as develop a therapeutic agent for intra-peritoneal micro-metastases from ovarian cancer.

Mr Wong said that Sirtex was undertaking a nanoparticle project with the University of Sydney and working with Melbourne's Peter MacCallum Cancer Centre.

He said that Sirtex was looking for commercial-ready technology that would capitalize on the company's knowledge and expertise.

Sirtex said the company benefitted by the fall of the Australian dollar against the US dollar.

The company said that revenue increased in all regions with the Americas up 42.5 percent to $136.7 million; Europe, the Middle East and Africa up 17.3 percent to $32.4 million; and Asia Pacific up 20.5 percent to $6.9 million.

Sirtex said that research and development expenditure increased 8.3 percent to $8,641,000, or 4.9 percent of total revenue.

The company said that net tangible asset backing per share was up 26.3 percent to $1.355 and diluted earnings per share increased 68.8 percent to 69.7 cents for the year to June 30, 2015 compared to 41.3 cents for the previous corresponding period.

The company said that a fully-franked dividend of 20.0 cents a share would be paid for shareholders on the record date of September 30 on October 21, 2015.

Sirtex said it had in cash and cash equivalents of $21,941,000 at June 30, 2015, compared to $22,495,000 at the end of the previous financial year.

Sirtex climbed $2.91 or 9.7 percent to $32.94 with 1.3 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says the European Commission has grant orphan designation to trofinetide (formerly NNZ-2566) for both Rett syndrome and Fragile X syndrome.

In February, Neuren said it had received US Food and Drug Administration orphan designation for trofinetide for Rett syndrome and it received orphan designation for Fragile X syndrome in 2013 (BD: Oct 30, 2013; Feb 16, 2015).

Today, Neuren said that EU orphan designation enabled sponsors to benefit from of incentives including 10 years of market exclusivity once the medicine was on the market and during the exclusivity period the EMA and member states would not accept another application for a marketing authorization for the same therapeutic indication for a similar medicinal product.

Neuren said it expected top-line results from its phase II trial of trofinetide for Fragile X syndrome in December 2015 and was preparing for the remaining development in Rett syndrome following its July meeting with the FDA (BD: Jul 29, 2015).

Neuren was up 0.1 cents or 1.05 percent to 9.6 cents with 3.7 million shares traded.

ACRUX

Acrux says that revenue for the 12 months to June 30, 2015 fell 52.9 percent to $25,368,000 with net profit after tax down 60.2 percent to $11,130,000.
Acrux chief financial officer Sharon Papworth told a teleconference that the previous year's revenue included recognition of $US25 million (then $A28.0 million) in milestone revenue from Eli Lilly for exceeding $US100 million in sales in a calendar year.
Acrux chief executive officer Michael Kotsanis told the teleconference that the company had acquired 12 generic topical and transdermal products separate to its previous pipeline that had an addressable market of $US2.4 billion.
Mr Kotsanis said that as generic products the development to registration timeline was shorter than for new drugs.
Mr Kotsanis said that two of the generic products were ibuprofen and diclofenac.
Mr Kotsanis said the estradiol product for symptoms of menopause, marketed in the US as Evamist, was expected to be available in Europe by July 2016.
Acrux said that net tangible asset backing per share was unchanged at 12 cents but diluted earnings per share fell 60.1 percent to 6.7 cents for the year to June 30, 2015 compared to 16.8 cents for the previous corresponding period.
The company said that a final 50 percent-franked dividend of six cents per share would be paid on September 3, for holders on the record date of August 20, 2015.
In 2014, Acrux paid a fully-franked dividend of eight cents a share (BD: Aug 21, 2014).
Acrux said it had in cash and cash equivalents of $23,068,000 at June 30, 2015, compared to $25,775,000 at the end of the previous financial year.
Acrux was up six cents or 9.0 percent to 73 cents with 2.9 million shares traded.

REVA MEDICAL

Reva expects to complete enrolment of the 110 patients in its Fantom II Conformité Européenne (CE) mark trial this year and file for approval in 2016.
In a teleconference, Reva's head of clinical and regulatory affairs Jeff Anderson said that the first cohort of 110 patients would provide data on the bioresorbable drug-eluting Fantom cardiac stent for CE mark approval (BD: Feb 25, Mar 16, 2015).
Mr Anderson said that the second cohort of 110 patients would be enrolled sequentially following the first 110 patient cohort.
Mr Anderson said that the second cohort would provide data on the longer term effects of the Fantom stent.
He said that the intention was to enrol patients at up to 30 centres and the company currently had 26 centres in eight countries outside the US enrolling patients.
Reva's most recent Appendix 4C Quarterly Report said that the company had a cash burn of $US4,476,000 for the three months to June 30, 2015 with cash at June 30, 2015 of $15,881,000.
Reva executive chairman Robert Stockman told the teleconference that warrants issued in 2014 could provide up to $22.8 million in further funds if exercised and the company had "secondary alternatives" if they weren't exercised.
Reva chief financial officer Katrina Thompson said that the warrants were exercisable at two prices, 25 cents per Australian Chess depository instrument (CDI) prior to concluding enrolment of the first cohort of 110 patients and at 30 cents per CDI after that milestone (BD: Sep 26, 2014).
Reva was untraded at 49 cents.

GENETIC SIGNATURES

Genetic Signatures says it has signed distribution deals for Ireland and Poland for its Easyscreen products.

Genetic Signatures said that the Dublin-based Medical Supply Co would distribute its products in Ireland and Northern Ireland which had a population of 6.5 million people.

The company said that the Poznan, Poland-based Argenta had been appointed distributor for Poland which had a population of 38 million people.

Genetic Signatures said that the products covered by the deals included its Easyscreen sample processing and pathogen detection kits and the GS1 automation platform.

The company said its Easyscreen sample processing and pathogen detection kits and the GS1 automation platform were available in Israel and Italy.

Genetic Signatures chief executive officer Dr John Melki said the “new distribution agreements support our strategy of global market penetration and increased market share”.

Dr Melki said that Conformité Européenne (CE) mark for in-vitro diagnostics “enable our products to be sold freely in all European Union member states, removing any regulatory hurdles”.

“The expanded distributor network now allows us to service a European population that is five times that of our Australian population,” Dr Melki said.

“We will continue to appoint distributors in further jurisdictions in the expectation of significant growth in Europe,” Dr Melki said.

Genetic Signatures was up half a cent or one percent to 48.5 cents.

GORDAGEN PHARMACEUTICALS

Gordagen says it has hired the Irvine, California-based Ascendiant Capital Markets as its US investment banker and corporate financial advisor.

Gordagen chief executive officer Dr Glenn Tong said he expected Ascendiant “to strengthen our financing opportunities and build institutional investor interest in the US as we execute our growth strategy and drive our products to market”.

The company said that Felda Wellness Corp was the cornerstone investor in its series A financing round completed in January 2014 and expressed support for the series B financing round (BD: Feb 4, 2014).

Gordagen said it was a private company developing and commercializing pharmaceuticals and food additives based on tocotrienols.

PRO MEDICUS

Perpetual and its subsidiaries say they have again reduced their holding in Pro Medicus below the five percent substantial level.

Perpetual said it became substantial with 5,296,892 shares (5.28%) on June 3, 2015, having reduced from 6,768,586 shares (6.85%) to 4,787,924 shares (4.8%) the previous week (BD: May 28, 2015).

Today, Perpetual said it sold shares between June 19 and August 10, at prices ranging from $2.10 to $2.49.

Pro Medicus was up five cents or 2.4 percent to $2.11 with 548,467 shares traded.

OBJ

OBJ says it will issue 2,000,000 shares to advisors Prof Anthony Wright and Dr Heather Benson to recognize their input to the scientific advisory committee.
OBJ said that Dr Benson and Prof Wright had helped guide development programs in skin biology and drug and peptide delivery.
The company said that the shares would be issued over two years.
OBJ was up half a cent or 6.85 percent to 7.8 cents with 3.4 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says former European Medicines Agency head Dr Thomas Lönngren will discuss EU regulation at its September 3, 2015 workshop.
The Network said that the workshop, entitled 'In Conversation with Thomas Lönngren: An Intimate EU-Global Regulatory Workshop' would explore strategies for entering the global market, especially via the European Union and provide opportunities for attendees to discuss their strategy questions with Dr Lönngren.
The Network said Dr Lönngren was the EMA executive director from 2001 to 2010 and was the Swedish Medical Products Agency deputy director general prior to the EMA.
Earlier this week, the former CBio director Dr Lönngren was appointed a director of Analytica (BD: Aug 10, 2015).
The Network said that pressure from patients and politicians to speed up regulatory systems to get earlier access to promising new medicines had increased and as a result, regulators had adopted initiatives to speed up the process.
Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "it is critical that companies keep pace with the changing regulatory landscape to refine their regulatory strategy and to inform their commercial strategies in taking products to market."
The Network said that the September 3, 2015 workshop would be held at the Spring Street Conference Centre, 1 Spring Street, Melbourne with registration from 2.15pm for the workshop from 2.30pm to 5.00pm, followed by a networking session.
To register go to: http://www.biomelbourne.org/events/view/379.