Biotech Daily

Wednesday February 24, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 12%, SIRTEX DOWN 7%**

*** SIRTEX H1 REVENUE UP 40% TO $113m, PROFIT UP 51% TO $27m**

*** EUROGOLD EGM TO DROP MINING FOR BARD1 LUNG CANCER TEST**

*** GORDAGEN, MONASH COLLABORATE ON DRUG DELIVERY CONCEPT**

*** IMUGENE PREPARES FOR PHASE Ib HER-Vaxx GASTRIC CANCER TRIAL**

*** JCR LAUNCHES MESOBLAST'S TEMCELL FOR GvHD IN JAPAN**

*** REVA COMPLETES FANTOM II TRIAL RECRUITMENT**

*** CYCLOPHARM REVENUE DOWN 1.5% TO $15m, PROFIT UP 18% TO $5m, DIVIDEND**

*** IMPEDIMED H1 REVENUE UP 30% TO $2.7m, LOSS UP 83% TO $11m**

*** CRYOSITE H1 REVENUE UP 10.5% TO $5m, PROFIT UP 8% TO $358k, DIVIDEND**

*** DORSAVI SIGNS PHYSIO CORP FOR VIPERFORM PILOT PROGRAM**

*** OPTISCAN TAKES FUNDRAISING HALT TO SUSPENSION**

*** FIL DECREASES, DILUTED TO 7% OF STARPHARMA**

*** PETER MEURS TAKES 21% OF DIMERIX**

*** YODAMBAO TAKES 6% OF DIMERIX**

*** GI DYNAMICS LOSES 2014 CEO MICHAEL DALE**

*** SIMON O'LOUGHLIN REPLACES TYRIAN'S DR CAROLINE POPPER**

MARKET REPORT

The Australian stock market fell 2.1 percent on Wednesday February 24, 2016 with the ASX200 down 104.6 points to 4,875.0 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and four were untraded.

Mesoblast was the best, up 20 cents or 12.35 percent to $1.82 with 1.1 million shares traded. Antisense climbed 6.25 percent; Ellex and Living Cell were up more than four percent; Clinuvel and Medical Developments were up more than three percent; Viralytics rose 2.3 percent; Prana was up 1.2 percent; with Cochlear up 0.1 percent.

Sirtex led the falls, down $2.43 or 6.7 percent to $33.75 with 770,617 shares traded. Orthocell lost 6.3 percent; Atcor, Oncosil and Pharmaxis fell more than five percent; Biotron and Impedimed fell more than four percent; Osprey was down 3.85 percent; Benited, Compumedics, Opthea and Prima shed two percent or more; with Admedus, IDT, Polynovo, Pro Medicus, Psivida, Starpharma and Resmed down more than one percent.

SIRTEX MEDICAL

Sirtex says that revenue for the six months to December 31, 2015 was up 40.0 percent to $112,596,000, with net profit after tax up 50.8 percent to $27,437,000.
Sirtex said that dose sales of its SIR-Spheres for liver cancer were up 15.7 percent to 5,728 units for the six months, implying an average cost of $19,657 per dose.
Sirtex said in the six months to December 31, 2015, dose sales in the Americas rose 18.8 percent to 4,028 doses, Asia Pacific sales were up 9.3 percent to 481 doses, with Europe, Middle East and Africa up 8.8 percent to 1,219 doses.
Sirtex chief executive officer Gilman Wong told a teleconference that the company had "record sales, record revenue and record net profit after tax".
Mr Wong noted that the company had recruited more than 95 percent of patients in two more major trials and the company had been promoted into the S&P ASX100, which could increase investor interest.
Mr Wong told the teleconference that the company was investing in research and development not for its own sake but to improve the lives of patients.
Sirtex chief financial officer Darren Smith said that gross margins on sales were up and volumes had increased, but those gains were partly offset by costs involved in commissioning the Frankfurt, Germany manufacturing facility.
Sirtex said that research and development expenditure increased 60.1 percent to $4,713,000 or 4.2 percent of revenue.
The company said that diluted earnings per share was up 46.2 percent to 44.6 cents, with cash and cash equivalents of $21,738,000 at December 31, 2015.
Sirtex said that net tangible asset per share increased 44.7 percent from $1.027 at December 31, 2014 to $1.488 at December 31, 2015.
Sirtex said that there would be no interim dividend but a fully-franked final dividend of 20 cents was paid on October 21, 2015 for the financial year to June 30, 2015.
Sirtex fell $2.43 or 6.7 percent to $33.75 with 770,617 shares traded.

EUROGOLD

Western Australian gold mining company Eurogold says it hopes to raise $3 million at two cents a share for the acquisition of Bard1 AG to develop a blood test for cancer.
Eurogold said in an announcement to the ASX in December 2015 and a notice of meeting today that it hoped to acquire the Swiss public company, founded in 2011 by the University Hospital of Geneva's the head of the molecular gynaecology and obstetrics laboratory Dr Irmgard Irminger-Finger.
The company said that Bard1 AG had developed "a simple blood test for screening and diagnosing lung cancer at early stages of disease progression".
Eurogold's notice of extraordinary general meeting said that Eurogold investors would vote on resolutions relating to the capital raising, a significant change in the nature and scale of activities and a name change to Bard1 Life Sciences.
The company said that shareholders would vote on the appointment of Dr Irminger-Finger as a director, along with the University of Western Australia's director of the centre for cell therapy and regenerative medicine Prof Geoffrey Laurent, who was also a member of Bard1's scientific advisory board.
The meeting will be held at DLA Piper Australia, Level 31, Central Park, 152-158 St Georges Terrace, Perth, Western Australia, on March 24, 2016 at 2pm (AWST).
Eurogold was untraded at three cents.

GORDAGEN PHARMACEUTICALS

Gordagen says it has a collaborative research agreement with Monash University to assess a new drug delivery technology.
Gordagen said the research project would assess the feasibility of a lymph-directing drug delivery technology developed by researchers at the Monash Institute for Pharmaceutical Sciences and was expected to be completed by October 2016.
The company said that the technology was expected to “help improve the bioavailability of tocotrienols, which forms the basis of Gordagen’s prescription medicines portfolio”.
Gordagen said the project would be led by Monash University’s Dr Chris Porter and would comprise synthesis of tocotrienol derivatives based on the new delivery technology.
The company said the molecules would be tested in validated animal models, initially providing data on the efficiency of absorption and bioavailability and pending a positive outcome, a licence for the technology as applied to tocotrienols would be negotiated.
Gordagen chief operating officer Dr Ric DeGaris said the proof-of-concept project could enable the company to expand its prescription medicines portfolio with new chemical entities protected by a composition of matter patent, under an exclusive licence.
Gordagen is a private company.

IMUGENE

Imugene says it hopes to begin a phase Ib dose-ranging trial of its HER-Vaxx B-cell producing immunotherapy for gastric cancer this year.
In an investor meeting in Melbourne, acting chief executive officer Leslie Chong said that Imugene was the only company in the world to develop the technology to activate B-cells which she described as “like antibody factories” to attack cancer cells.
Ms Chong said that with the Medical University of Vienna, the technology had been optimized to incorporate three B-cell epitopes into a single peptide, delivery systems were changed and an adjuvant added, leading to a 10-fold increase in antibody response.
Imugene’s chief technical officer Dr Nick Ede said that all the pre-clinical work had been completed with results pending and the company expected to file applications to regulators in Hong Kong, Thailand and Taiwan “in the next few weeks” with doses and kits expected to be ready for in April.
Ms Chong said that a 10-patient, phase I trial in Vienna in 2009 showed responses in eight of the 10 patients and the technology had been developed significantly since Imugene acquired it (BD: Oct 23, 2013; Jan 25, 2016).
Ms Chong said that Novotech would be contract research organization running the trial in Asia, with results expected by July 2017.
She said that the company had planned an open-label, randomized, 68-patient, phase II trial to follow by the end of 2017, with results by the end of 2019.
Ms Chong said that median progression-free survival for gastric cancer was four months and median overall survival was 14 months and she expected the number of patients in the phase II trial to provide statistically significant results.
Ms Chong said that with $4 million in cash the company had funds for the next 12 months including the start of the phase Ib trial.
Imugene’s head of corporate development Stuart Roberts said that with 480,177,356 options on offer, exercisable “on average” at 1.55 cents each in 2017, the company only needed to improve its profile and share price in order to raise up to $7.5 million through the exercise of options.
Mr Roberts said that at 1.5 cents the exercise of options would yield about $6 million.
Imugene was unchanged at one cent with 5.1 million shares traded.

MESOBLAST

Mesoblast says Japan licencee JCR Pharmaceuticals has launched its Temcell mesenchymal stem cell product for the treatment of acute graft versus host disease.
Mesoblast said that Temcell the first allogeneic cell therapy to be fully approved in Japan and the Japanese Government's National Health Insurance set reimbursement at YEN868,680 ($A19,828) per bag of 72 million cells.
The company said that the average adult patient in Japan was expected to receive at least 16 or up to 24 bags of 72 million cells, meaning that a treatment course would be reimbursed at YEN13,898,880 to YEN20,848,320 ($A173,236 to $A259,854).
Mesoblast said that under the agreement with JCR, it was entitled to royalties and other payments at predefined thresholds of cumulative net sales.
Mesoblast was up 20 cents or 12.35 percent to $1.82 with 1.1 million shares traded.

REVA MEDICAL

Reva says it has completed enrolment of its 110-patient second cohort for the Fantom II trial of its bio-resorbable coronary scaffold, taking total enrolment to 227 patients.
Reva said the trial was examining the safety and performance of the drug-eluting Fantom stent with six-month data on a subset of patients in the first cohort to be presented at the Paris Course on Revascularization in May 2016.
The company said that data from patients in the second cohort was intended to provide further clinical evidence on the use of Fantom to treat coronary artery disease and would be used for market support and other commercial purposes, with second cohort data to be released at conferences, beginning at the Transcatheter Cardiovascular Therapeutics Conference in October 2016.
Reva chief executive officer Dr Reggie Groves said that completion of the targeted enrolment was "another important milestone for the company".
The company said that seven additional patients had been added to the first cohort, which was undergoing a six-month imaging assessment and data from these patients would be used in a Conformité Européenne (CE) mark application to be filed by October 2016.
Reva was untraded at $1.13.

CYCLOPHARM

Cyclopharm says that revenue for the 12 months to December 31, 2015 fell 1.5 percent to $14,733,418 increasing net profit after tax by 17.9 percent to $4,793,047.
Cyclopharm said that record sales revenue was up 4.4 percent to $12,582,519, but "other revenue" relating to litigation and insurance settlements fell by $790,231.
The company said it proposed to pay a fully-franked final dividend of 0.5 cents on April 19, for investors at the record date of April 12, 2016, having paid an interim fully-franked dividend of 0.5 cents.
Cyclopharm managing director James McBrayer said that 2015 was "another year of outstanding progress [and] by concentrating on opportunities to leverage our Technegas technologies in 2014, Cyclopharm is a more focused, profitable, cash generative business supported by a healthy balance sheet and an active research and development pipeline".
Cyclopharm said that diluted earnings per share increased 18.8 percent to 8.35 cents with net tangible assets per share up 66.7 percent from 12 cents to 20 cents.
Cyclopharm said it had $6,444,995 in cash and equivalents at December 31, 2015 compared to $3,268,425 for the previous corresponding period.
Cyclopharm was up 0.5 cents or 0.8 percent to 60 cents.

IMPEDIMED

Impedimed says that revenue for the six months to December 31, 2015, was up 29.6 percent to $2,735,000 with net loss after tax up 83.2 percent to $11,215,000.
Impedimed said the sales of good, namely its L-Dex U400 lymphoedema test increased 30.9 percent to $2,580,000 with services up 15.9 percent to $131,000.
The company said that diluted loss per share was up 33.3 percent to four cents for the six months to December 31, 2015, while net tangible assets per share fell 38.5 percent to eight cents at December 31, 2015 compared to 13 cents at December 31, 2014.
The company said it had cash and cash equivalents of $25,152,000 at December 31, 2015, compared to $32,582,000 at June 30, 2015.
Impedimed fell four cents or 4.2 percent to 91 cents.

CRYOSITE

Cryosite says revenue for the six months to December 31, 2015, was down 2.6 percent to $4,956,000 with net profit after tax down 42.3 percent to $207,000.
Cryosite said that it provided cord blood storage, bio-repository management and distribution of biological materials and pharmaceutical products used in clinical trials.
The company said that while revenue was “marginally less … [it had] several significant longer term positive revenue gains recorded in key service areas in both biological and warehousing and distribution … during the current period”.
Cryosite said it would pay an interim unfranked dividend of 0.5 cents a share with a record date of March 15 to be paid on March 31, 2016.
The company said that net tangible assets per share fell 9.6 percent to 6.6 cents with diluted earnings per share down 42.1 percent to 0.44 cents at December 31, 2015 compared to 0.76 cents for the previous corresponding period.
Cryosite said that cash and cash equivalents at December 31, 2015 was $4,106,959 compared to $4,167,302 at June 30, 2015.
Cryosite was up one cent or 5.4 percent to 19.5 cents.

DORSAVI

Dorsavi says the Exton, Pennsylvania-based Physio Corp has signed an initial pilot program offering its wearable wireless sensors to assess sports medicine patients.
Dorsavi said that Physio was a physical and occupational outpatient rehabilitation services provider with more than 540 clinics across 29 US states and the initial focus would be movement analysis in running and knee assessments.
The company said that the agreement included the implementation of 20 Viperform units across 20 sites during the first 12-months.
Physio’s sport medicine director Dr Trent Nessler said that the collaboration with Dorsavi “fits perfectly with Physio’s long standing mission to continuously innovate and deliver patient focused, evidence based care”.
“Apart from running and knee assessments we see other use cases for Dorsavi’s wearable technology across a number of our business areas,” Dr Nessler said.
Dorsavi said that Physio treated more than 300,000 patients a year and provided athletic trainers to more than 200 schools, 26 universities and 20 professional teams.
The company said that with more than 200,000 anterior cruciate ligament injuries in youth athletics in the US, there was a need to create tools that were reliable and scalable for mass physicals and for use in clinics.
Dorsavi was unchanged at 36 cents.

OPTISCAN

Optiscan has requested a voluntary suspension to follow the trading halt requested on February 19, “pending an announcement … concerning fundraising” (BD: Feb 22, 2016).
Optiscan last traded at two cents.

STARPHARMA

FIL Limited says it has decreased its holding and been diluted in Starpharma from 25,675,108 shares (8.01%) to 25,285,196 shares (6.89%).
The Sydney and Hong Kong-based FIL said it bought shares between January 21 and 28 including in a share purchase plan at 73 cents a share as well as on-market at 63 and 64 cents a share and sold shares between February 12 and 19 and 55 to 57 cents a share.
Starpharma fell one cent or 1.6 percent to 60 cents.

DIMERIX (THEN SUN BIOMEDICAL)

The South Melbourne-based Peter Meurs says he has increased his shareholding in Dimerix from 264,236,879 shares (19.96%) to 290,660,567 shares (20.78%).
The substantial shareholder notice said that the increase followed the conversion of performance shares for nil consideration (BD: Feb 19, 2016).
Dimerix was down 0.1 cents or 16.7 percent to 0.5 cents with 7.8 million shares traded.

DIMERIX (THEN SUN BIOMEDICAL)

The Dalkeith, Western Australia-based Yodambao Pty Ltd has increased its substantial shareholding in Dimerix from 77,886,197 shares (5.88%) to 85,674,817 shares (6.13%).
The substantial notice, signed by director Tracy Blake, said that the increase followed the conversion of performance shares for nil consideration (BD: Feb 19, 2016).

GI DYNAMICS

GI Dynamics says that chief executive officer Michael Dale will resign effective from March 15, 2016 “to pursue other professional opportunities”.
GI Dynamics thanked Mr Dale for his contribution and said it would begin a search for a replacement chief executive officer.
In 2014, Mr Dale was appointed chief executive officer and a director replacing Stuart Randle, effective from September 18, 2014.(BD: Aug 29, 2014).
In October 2014, European Union shipments of the Endobarrier duodenal liner for obesity and type 2 diabetes were halted and later cleared for sales, followed by chief financial officer Bob Crane being “separated” from the company (BD: Oct 6, 7; Dec 1, 9, 2014).
In March 2015, following four cases of bacterial liver infections, the US Food and Drug Administration halted enrolment in the Endobarrier pivotal trial (BD: Mar 6, 2015).
The company said it hoped to restart its US trial in July 2015, but in June dismissed chief medical officer Dr David Maggs and later terminated the trial saying the US protocol might have caused the hepatic abscesses (BD: May 6, June 19, Jul 30, 31, 2015).
GI Dynamics was up 0.1 cents or five percent to 2.1 cents.

TYRIAN DIAGNOSTICS

Tyrian says Simon O'Loughlin will replace Dr Caroline Popper as a non-executive director.
Tyrian chairman Roger Amos thanked Dr Popper for her eight years on the board.
The company said that Mr O'Loughlin was the founder of the Adelaide-based commercial law firm O'Loughlins Lawyers and had experience in corporate and commercial law and held accounting qualifications.
Tyrian said that Mr O'Loughlin was currently a non-executive director of Lawson Gold, WCP Resources, Xref, Chesser Resources, Petratherm and Oklo Resources.
In 2012, Tyrian's key staff, including chief executive officer Dr Jenny Harry resigned and said it had it had disposed of all fixed assets, ceased all further research and development work and vacated its facility at North Ryde (BD: Feb 24, 2012).
The company said at that time that the termination of agreements by Bayer Cropscience triggered the review and staff terminations (BD: Aug 24, 2011).
Tyrian was unchanged at 0.1 cents with 4.3 million shares traded.