



Biotech Daily

Wednesday August 14, 2013

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH UP: NEUREN UP 14%, AVITA DOWN 4%
- * CSL RECORD PROFIT UP 19% TO \$1,338m, REVENUE UP 7% TO \$5,642m
- MARIE MCDONALD REPLACES DIRECTOR IAN RENARD
- * SUDA COMPLETES NOVADEL ACQUISITION
- * NANOSONICS REVENUE UP 35% TO \$17.6m, LOSS UP 23% TO \$5.8m
- * LABOR NAMES MEDICAL TECHNOLOGY '1st INNOVATION PARTNERSHIP'
- * BIOTA CLEARS WAY FOR UP TO \$82m CAPITAL RAISING
- * BIOTRON BIT225 CAPSULE INCREASES BIOAVAILABILITY 1.6-FOLD
- * ELLEX PROFIT WARNING
- * CORRECTION: SUNSHINE HEART
- * CLARIFICATION: GI DYNAMICS
- * GREENLIGHT TAKES 7% OF GI DYNAMICS
- * JASON PETERSON, CELTIC CAPITAL BELOW 5% OF IMUGENE
- * BLUECHIIP REQUESTS CAPITAL RAISING TRADING HALT

MARKET REPORT

The Australian stock market slipped 0.01 percent on Wednesday August 14, 2013 with the S&P ASX 200 down 0.3 points to 5,157.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and three were untraded. All Big Caps fell.

Neuren was the best, up 1.5 cents or 14.3 percent to 12 cents with 11.7 million shares traded, followed by Nanosonics up 12.3 percent to 86.5 cents with 830,579 shares traded. QRX climbed 8.4 percent; Antisense and GI Dynamics were up more than seven percent; both Patrys and Viralytics were up five percent; Alchemia, Atcor and Starpharma were up four percent or more; Bionomics and Genetic Technologies were up more than three percent; Universal Biosensors rose 2.9 percent; Clinuvel, Osprey and Prana were up more than one percent; with Sirtex up 0.3 percent.

Avita was down half a cent or 3.85 percent to 12.5 cents with 87,140 shares traded. Allied Health, CSL and Medical Developments were down three percent or more; Optiscan, Prima and Resmed shed more than two percent; Acrux, Ellex and Heartware were down more than one percent; with Cochlear and Mesoblast down less than one percent.

CSL

CSL says its record net profit after tax was up 18.75 percent to \$US1,216 million (\$A1,337.6 million) for the 12 months to June 30, 2013 on record revenue up 6.6 percent to \$US5,129 million (\$A5,641.9 million).

CSL said that its total ordinary dividend was up 16 US cents or 18 percent to \$US1.02 (\$A1.056) a share with the final dividend up three US cents to 52 US cents a share.

CSL chief executive officer Paul Perreault told a teleconference that the credit for the result went to his predecessor as chief executive officer, Dr Brian McNamee.

"On all metrics this is an excellent result for the company demonstrating our ongoing ability to leverage our scientific expertise, operational excellence and global commercial footprint for continued growth and success," Mr Perreault said.

Mr Perreault said there had been an increase in use of immunoglobulins, albumin and specialty products along with US approval for Kcentra for urgent warfarin reversal.

Mr Perreault said that \$US450 million had been spent on capital works including nine new blood collection centres in the US taking the total to 80 US collection centres.

Mr Perreault forecast a 10 percent increase in net profit after tax for the coming year with earnings per share expected to exceed the profit.

The company said that diluted earnings per share was up 23.6 percent \$US2.431, while net tangible asset backing per share fell 14.4 percent from \$US5.15 to \$US4.41.

CSL said that research and development spending was up 32.3 percent to \$US427 million (\$A469.7 million) compared to last year's \$A355 million, and was 8.3 percent of revenue.

"Our research and development spend is forecast to grow faster than our growth in profit as we approach commercialization of several recombinant coagulation products currently in development," Mr Perreault said in a media release.

CSL had cash and cash equivalents fell 34.95 percent to \$US762 million.

Mr Perreault said that the current share buy-back was 97 percent completed and the company was considering a further buy-back of about the same size.

CSL said that director Ian Renard would retire at the conclusion of its annual general meeting on October 16, 2013 and Marie McDonald had been appointed a director, effective from today August 14, 2013.

CSL said that Ms McDonald was a partner at Melbourne law firm Ashurst and had a background in corporate and commercial law.

CSL said Ms McDonald was a member of the Australian Takeovers Panel from 2001 to 2010 and held Bachelor of Science and Laws degrees from the University of Melbourne.

CSL fell \$2.01 or 3.0 percent to \$65.79 with 2.5 million shares traded.

SUDA

Suda says it has completed the acquisition of the Novadel Pharma assets and the Novamist technology has been renamed Sudamist (BD: April 8, 2013).

Suda said that Sudamist was a system to deliver a broad range of marketed drugs through the lining of the mouth.

The company said it held "an extensive and robust patent portfolio with further patents pending" covering more than 300 pharmaceutical compounds and a clinically advanced product portfolio that was commercialization ready.

Suda said the portfolio included oro-mucosal forms of delivery for erectile dysfunction (sildenafil); migraine headache (sumatriptan); chemotherapy induced nausea and vomiting (ondansetron); pre-procedural anxiety (midazolam); and pulmonary arterial hypertension (sildenafil).

Suda was up 0.1 cents or 3.45 percent to three cents with one million shares traded.

NANOSONICS

Nanosonics says that revenue for the 12 months to June 30, 2013, was up 35 percent to \$17,589,000, with net loss after tax up 23 percent to \$5,768,000.

Nanosonics said that revenue from Trophon EPR ultrasound probe cleaning units and consumables increased by 21 percent to \$14.9 million, largely driven by sales to North America distributor GE Healthcare and the increased loss was related to an increased investment in market development.

In a separate announcement, Nanosonics said GE Healthcare had created a dedicated sales team for the Trophon EPR and GE Ventures would make “a non-dilutive investment to fund a fully integrated marketing program”.

Nanosonics chief financial officer McGregor Grant told Biotech Daily that the investment was “material but commercially confidential” and would cover increasing market awareness through conferences and key opinion leaders.

In a media release, Nanosonics chief executive officer Dr Ron Weinberger said the Trophon EPR was gaining traction in North America and there was an “increasing recognition of the need to utilize safer and more reproducible high level disinfection of ultrasound probes”.

The company said that Nanosonics was focused on increasing market penetration in the UK and Europe and had signed Toshiba as a non-exclusive partner in the UK and had submitted regulatory dossiers for the Trophon EPR in Mexico, Korea and Japan.

Nanosonics said that net tangible assets per share fell 17.3 percent to 8.1 cents, with diluted loss per share up 10.0 percent to 2.2 cents.

The company said that it had cash and cash equivalents of \$24,064,000 at June 30, 2013 compared to \$29,310,000 at June 30, 2012.

Nanosonics climbed 9.5 cents or 12.3 percent to 86.5 cents.

FEDERAL AUSTRALIAN LABOR PARTY

The Federal Australian Labor Party says the Medical Technologies Innovation Partnership at Macquarie Park in Sydney is the first Australian Innovation Partnership.

A campaign media release, from Prime Minister Kevin Rudd and the Minister for Innovation, Industry, Science and Research Senator Kim Carr, said the Innovation Partnerships were “a key part of Federal Labor’s positive plan to support jobs for Australia beyond the mining investment boom”.

The media release said that medical technologies were “a key industry of the future” with the global medical technology market valued at more than \$US300 billion a year and expected to approach US\$350 billion by 2016.

The Labor Party media release said that the Medical Technologies Innovation Partnership would “develop an industry-led strategy for future growth based on a highly skilled workforce, innovation, accessing global markets and sufficient scale to attract international investment and partnerships”.

The ALP said that the Partnerships built on the first two Innovation Precincts, in food and manufacturing, established under the \$1 billion Plan for Australian Jobs package and Labor would provide an additional \$12 million in funding to expand the original 10 precincts to 12 Australian Innovation Partnerships to build national networks, involving hundreds of firms, to translate research into commercial outcomes.

In February, the Government announced its ‘Industry and Innovation’ policy including \$504.5 million to establish up to 10 Industry Innovation Precincts to drive productivity, improve connections between business and the research sector and mobilize industry to compete more successfully in global markets (BD: Feb 18, 2013).

BIOTA PHARMACEUTICALS

Biota has filed an S3 Registration Statement with the US Securities and Exchange Commission to raise up to \$US75,000,000 (\$A82,442,000).

Biota told the SEC that the application covered common stock, preferred stock, debt securities, warrants and units with the date of commencement of a proposed sale to the public "from time to time after the effective date of this Registration Statement".

Earlier this year, Sunshine Heart filed a similar Registration Form with the SEC for up to \$US75,000,000 and the following week announced it had raised about \$US14.0 million (BD: April 11,12, 17, 2013).

Today Biota said that apart from "as described in any applicable prospectus supplement and in any free writing prospectuses in connection with a specific offering, we currently intend to use the net proceeds from the sale of the securities offered hereby for general corporate purposes, including research and development, licence or technology acquisitions, expansion and the development of our products and general administrative expenses, working capital and capital expenditures ...[and] pending these uses, we intend to invest the net proceeds in investment-grade, short-term interest-bearing securities".

Last night on the Nasdaq, Biota was up 12 US cents or 2.98 percent to \$US4.15 (\$A4.57, equivalent to 57.1 cents pre-merger) with 31,760 shares traded.

BIOTRON

Biotron says it has developed a capsule formulation of its lead hepatitis C and HIV drug candidate BIT225.

Biotron said that an Australian 14-patient phase I study of the new formulation developed with a US formulation company, demonstrated that the capsule was "associated with reproducible absorption and a relative bioavailability more than 1.6 times greater than the previous powder formulation".

The company said the 14 participants were randomized to receive 400mg of BIT225 as a single dose of either the new capsule or the existing powder formulation and followed up with extensive blood sampling over a 96-hour period.

Biotron said that two weeks later, participants received the alternate formulation and further blood samples were taken over the same period.

The company said that analysis of the samples demonstrated that blood levels of BIT225 were more than 1.6 times higher following capsule delivery and in future trials, lower doses of the drug could be delivered by capsule than in previous trials.

Biotron managing director Dr Michelle Miller said the capsule formulation had the potential to further enhance the safety profile of BIT225 and would facilitate extended trials in larger patient populations.

"In essence, this trial has demonstrated we can use lower doses of BIT225 to achieve higher blood levels of the compound in patients safely and efficiently," Dr Miller said.

"This is an important milestone as we progress commercialization of this first in class drug," Dr Miller said.

"These results bolster BIT225's overall data package and increase its appeal to potential licensing partners," Dr Miller said.

Biotron said that it expected to use the BIT225 capsules in a three month phase IIb hepatitis C trial later this year.

"The ability to conduct further trials of this compound with a new patient and trial friendly capsule formulation further improves the drug's profile and its longer term prospects as a new therapeutic to help manage these serious diseases," Dr Miller said.

Biotron was up 0.3 cents or 3.5 percent to 8.8 cents.

ELLEX MEDICAL LASERS

Ellex says it expects net profit before tax to be between \$100,000 and \$200,000 for the year ended June 30, 2013 compared to \$1.1 million for the year ended June 30, 2012.

The company said it expected to release its full year results by the end of August.

Ellex chief executive officer Tom Spurling said that foreign exchange posed "challenges for our business".

Ellex said revenue was expected to be 9.8 percent lower compared to the 2011-'12 financial year in which the company had a non-recurring sale.

After allowing for this, revenue for the year to June 30, 2013 fell by about 3.5 percent.

Ellex fell 0.5 cents or 1.9 percent to 26 cents.

SUNSHINE HEART

In yesterday's edition the equivalent Australian value for Sunshine Heart US shares before the company left the ASX was given as 3.7 cents.

The correct amount should have been 4.7 cents.

The US Data Conversion Sub-Editor has replaced her calculator and bought new batteries.

Last night on the Nasdaq, Sunshine Heart was up 57 US cents or 6.698 percent to \$US9.09 (\$A10.00, equivalent to 5.0 cents before the company left the ASX) with 179,692 shares traded

GI DYNAMICS

Last night's edition said that in 2011 that Medtronic held 12.76 percent of GI Dynamics when it listed on the ASX and following the \$60 million capital raising it held 39,115,442 Chess depositary interests (CDIs) or 9.77 percent of the company.

A GI Dynamics representative told Biotech Daily today that while other investors reduced or held and were diluted in the capital raising, Medtronic increased its holding from 35,341,858 CDIs (12.76%) to 39,115,442 CDIs (9.77%).

No sub-editors were hurt in making this clarification.

GI Dynamics was up five cents or 7.7 percent to 70 cents.

GI DYNAMICS

Greenlight Capital has increased its substantial shareholding in GI Dynamics from 19,414,494 Chess depositary interests (CDIs) (5.40%) to 28,301,887 CDIs (7.07%).

The New York-based Greenlight failed to complete the substantial shareholder notice correctly but Biotech Daily believes the company participated in the recent \$60 million capital raising at 53 cents a share (BD: Jul 3, 2013).

IMUGENE

Jason Peterson and Celtic Capital have been diluted below substantial in Imugene.

In June, an Imugene share plan raised \$183,000 through applications for 33,888,932 shares at 0.54 cents a share and in July 100,000,000 shares were released from ASX escrow (BD: Jun 4, Aug 2, 2013).

Last year, the Perth, Western Australia-based Jason Peterson and Celtic Capital became substantial in Imugene with the 21,000,000 shares or 8.6 percent (BD: Aug 13, 2012).

Imugene fell 0.05 cents or 7.1 percent to 0.65 cents.

BLUECHIIP

Bluechiip has requested a trading halt “pending an announcement to the market in connection with a proposed capital raising”.

Trading will resume on August 16, 2013 or on an earlier announcement.

Bluechiip last traded at 17.5 cents.