



# Biotech Daily

Wednesday August 17, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: LIVING CELL UP 12%, IDT DOWN 8.5%**
- \* **CSL PROFIT DOWN 10% TO \$1.6bn, RECORD REVENUE UP 9% TO \$8bn**
- \* **COGSTATE REVENUE UP 69% TO \$27m, LOSS TO PROFIT OF \$2.6m**
- \* **NANOSONICS MAIDEN \$122k PROFIT ON SALES UP 93% TO \$43m**
- \* **USCOM REVENUE UP 44% TO \$2.9m, LOSS UP 58% TO \$1.9m**
- \* **REVA AWAITING TRIAL RESULTS, SALES READY, CASH TO APRIL 2017**
- \* **US GRANTS MESOBLAST 2 RHEUMATOID ARTHRITIS PATENTS**
- \* **REPRODUCTIVE HEALTH LAUNCHES DOPLIFY FOR GENE TESTING**
- \* **MEDIBIO, UNIVERSITY OF SYDNEY CARDIAC STRESS TEST TRIAL**
- \* **CRYSTAL AMBER TAKES 13% OF GI DYNAMICS**
- \* **MEDLAB CEO SEAN HALL INCREASES, DILUTED TO 31.5%**
- \* **LIVING CELL PLEADS SCHULTZ TO ASX 25% QUERY**
- \* **ACTINOGEN UNMARKETABLE PARCEL FACILITY**
- \* **DR TADATAKA YAMADA REPLACES CSL DIRECTOR JOHN AKEHURST**

## MARKET REPORT

The Australian stock market edged up 0.05 percent on Wednesday August 17, 2016 with the ASX200 up 3.0 points to 5,535.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine were unchanged and three were untraded. All three Big Caps fell.

Living Cell was the best on an ASX query, up 0.9 cents or 12 percent to 8.4 cents with 3.9 million shares traded. Uscom climbed 8.2 percent; Mesoblast was up 6.6 percent; Actinogen improved 5.1 percent; Osprey was up 4.8 percent; Compumedics climbed 3.5 percent; Admedus, Avita, Pharmaxis, Pro Medicus and Viralytics rose more than one percent; with Ellex and Starpharma up by less than one percent.

Yesterday's best, IDT, led the falls, down two cents or 8.5 percent to 21.5 cents with 12,200 shares traded. CSL, Genetic Technologies and Prima fell more than five percent; Acrux, Anteo, Benitec, Bionomics and Impedimed lost more than three percent; Opthea and Reva shed more than two percent; Medical Developments lost 1.1 percent; with Airxpanders, Clinuvel, Cochlear, Psivida, Resmed and Sirtex down less than one percent.

## CSL

CSL says its net profit after tax for the 12 months to June 30, 2016 fell 9.9 percent from last year's record profit of \$US1,379.0 million to \$US1,242 million (\$A1,612.8 million) on record revenue up 8.9 percent to \$US6,129 million (\$A7,958.6 million).

CSL reported its headline numbers as revenue up 8.2 percent to an "underlying" \$US6,089 million "at constant currency" with underlying net profit after tax up 5.2 percent to \$US1,437 million, recalculating the numbers to allow for foreign exchange rate changes, as well as the \$US90 million cost of the Novartis influenza vaccines business acquisition (BD: Oct 27, 2014; Jul 31, Aug 3, 2015).

CSL attributed the fall in profit to the cost of the Novartis acquisition.

CSL chief executive officer Paul Perreault told a teleconference that the company had won approvals and launched five new products in its "transformational" centennial year, notably CSL Behring's recombinant factor IX Idelvion, the recombinant factor VIII Afstyla and Respreeza, along the Seqirus influenza division's Fluad, Flucelvax and Afluria Quad. Mr Perreault said that revenue increases came from its immunoglobulin, haemophilia, albumin and speciality products, with Hizentra sales up 31 percent and Privigen sales up seven percent; haemophilia product sales up four percent in constant currency but the CSL slide showed that revenue fell 2.5 percent to \$US1,000 million; while speciality products sales increased 5.85 percent; and albumin sales up 26 percent in China.

He said that the integration of the Seqirus business was "substantially completed" taking the previous Bio-CSL influenza, pharmaceuticals and vaccines revenue from \$US412 million in the year to June 30, 2015 to \$US652 million in the year to June 30, 2015 and allowing for "a mild 'flu season" in the Northern Hemisphere.

Mr Perreault said he expected revenue to increase by nine percent and net profit after tax to increase by 11 percent, both at constant currency in the coming financial year.

CSL said that a final unfranked dividend of 68 US cents per share would be paid to shareholders at the record date of September 14, 2016 following the unfranked interim dividend of 58 US cents a share paid on April 15, 2016.

CSL said that its net tangible asset backing per share fell 9.2 percent from \$US3.92 to \$US3.56 with diluted earnings per share down 7.9 percent to \$US2.914.

The company said that research and development spending increased 32.7 percent to \$US613.8 million compared to the previous year, and was 10.0 percent of total revenue compared to the previous year's 8.2 percent of revenue.

CSL said it had \$US556.6 million in cash and cash equivalents at June 30, 2016, nearly identical to the previous corresponding period's \$US556.8 million.

Mr Perreault said the company's eighth share buy-back was 92 percent completed and there would be a further \$500 million buy-back as well as a \$US500 million placement.

CSL fell \$5.91 or 5.1 percent to \$110.84 with 3.2 million shares traded.

## COGSTATE

Cogstate says revenue for the 12 months to June 30, 2016 was up 68.5 percent to \$27.3 million taking last year's net loss after tax to a net profit after tax of \$2.6 million.

Cogstate said that its clinical trial business was the main source of revenue up 68.4 percent to \$25.6 million, with its recruitment diagnostic business earning \$1.59 million.

The company said that net tangible asset backing per share increased 12.5 percent to nine cents, diluted earnings per share was 2.3 cents compared to the previous year's loss of 5.1 cents, with \$7,471,284 in cash and equivalents at June 30, 2016 compared to \$5,497,197 for the previous corresponding period.

Cogstate fell three cents or 3.8 percent to 76 cents.

## NANOSONICS

Nanosonics has posted its maiden full-year profit of \$122,000 on record revenue up 73 percent to \$44,027,000 for the 12 months to June 30, 2016.

Nanosonics said that Trophon EPR sales revenue was up 92.8 percent to \$42.8 million for the 12 months to June 30, 2016

The company said its net loss after tax for the year to June 30, 2015 was \$5.5 million.

Nanosonics chief executive officer Michael Kavanagh said that the 2016 financial year "has been one of significant achievement and success".

"The fundamentals for the adoption of our technology continued to grow throughout the year resulting in excellent growth in the installed base in particular in North America where the installed base grew 74 percent to over 8,700 units," Mr Kavanagh said.

Nanosonics said research and development spending increased 50 percent to \$7,297,000 or 16.6 percent of revenue, with staff numbers increased by 18 percent to 150 employees. The company said that net tangible asset backing per share was up 22.4 percent to 19.1 cents and the diluted loss per share of 2.03 cents at June 30, 2015 had been turned around to diluted earnings per share of 0.04 cents.

The company said it had cash and cash equivalents of \$48,841,000 at June 30, 2016.

Nanosonics was unchanged at \$2.80.

## USCOM

Uscom says that revenue for the year to June 30, 2016, was up 44.0 percent to \$2,936,504 with net loss after tax up 58.0 percent to \$1,915,029.

Uscom executive chairman Prof Robert Phillips told Biotech Daily that the revenue increase was primarily from sales of Uscom 1A ultra-sonic cardiac output monitor.

Uscom said that net tangible asset per share was up 106.7 percent to 0.03.1 cents, with diluted loss per share up 33.3 percent to 2.0 cents.

The company said that it had cash and cash equivalents of \$2,839,773 at June 30, 2016 compared to \$526,317 at June 30, 2015.

Uscom was up 2.5 cents or 8.2 cents to 33 cents.

## REVA MEDICAL

Reva chief executive officer Dr Reggie Groves says that the Fantom stent second cohort results are expected in September and the company has funds to April 2017.

In a teleconference, Dr Groves said that the \$US16.6 million in cash at June 30, 2016 was "sufficient for our near-term strategy" which was on-track.

In its Appendix 4C quarterly report for the three months to June 30, 2016, Reva said its cash burn was \$US5.4 million, providing about nine months cash.

Dr Groves said the company's priorities were Conformité Européenne (CE) mark approval for the Fantom scaffold, which was possible by the end of 2016; commercialization of the scaffold, including scale-up of manufacturing, sales and marketing and negotiations with Boston Scientific on its potential sales and distribution of the stent; and capital raising.

Dr Groves said that even if the European approval went smoothly, revenue would take time to be received and there would be a need for a capital raising "at the lower end".

Dr Groves said that a number of issues needed to be considered including the cost of a US approval trial, estimated at about \$US75 million.

Dr Groves said the last patient of 125 patients in the second cohort of the Fantom II trial was treated in March, with results from the two-part trial expected in September 2016.

Reva fell three cents or 2.3 percent to \$1.25.

## MESOBLAST

Mesoblast says the US Patent and Trademark Office has granted “a key patent” covering its mesenchymal precursor cells for rheumatic diseases.

Mesoblast said that its US patent estate for rheumatoid arthritis and related conditions comprised the newly and recently granted patents, entitled ‘Methods of generating, repairing and/or maintaining connective tissue in vivo’ providing coverage to July 29, 2030 and ‘Methods of treating or preventing rheumatic disease’ providing cover to July 4, 2032. The company said that the patents covered treatment of rheumatic diseases by administration of STRO-1 positive mesenchymal precursor cells.

Mesoblast said that the granted claims covered the use of the cell populations to reduce levels of inflammatory cytokines tumor necrosis factor-alpha, interleukin-6, and interleukin-17, which were established mediators of inflammatory arthritis in rheumatic diseases.

Mesoblast was up 10 cents or 6.6 percent to \$1.605 with 1.9 million shares traded.

## REPRODUCTIVE HEALTH

Reproductive Health Science says it launched its Doplify in early July.

Reproductive Health said that Doplify was launched at the European Society of Human Reproduction and Embryology meeting in Helsinki, Finland, July 3 to 6, 2016.

The company said that Doplify was its second product after its Embryocollect product which analyzed of embryos for in-vitro fertilization.

The company said that Doplify was a “next generation sequencing” product which multiplied “the limited DNA in a single cell for a range of downstream applications”.

Reproductive Health chief executive officer Dr Michelle Fraser said that Doplify had “significant performance advantages over other products … [providing a platform] to expand our target market into such areas as understanding cancer, plant and animal science and forensics as well as broader clinical and research applications”.

The company said that Doplify could screen an embryo for changes in chromosome number and at the same time detect the presence of a genetic disease that needed to be avoided during embryo transfer, such as Duchenne’s muscular dystrophy.

Reproductive Health fell 0.8 cents or eight percent to 9.2 cents.

## MEDIBIO

Medibio says the University of Sydney will use its mental health test with an unnamed corporate for a workplace stress assessment clinical research study.

Medibio said that study would investigate the potential relationship between an individual’s mood and stress levels and circadian heart rate patterns and investigate if symptoms of anxiety and depression were associated with distinctive pattern deviations in cardiac rate. The company said that pending the results, the product could be rolled out across the unnamed customer’s 10,000 staff.

Medibio said that 135 of the 150 participants had undergone the first of two stress tests and psychiatric measures, with the first phase to be completed by the end of the month.

Medibio said that the two phase study would use its stress test, which categorized individuals in six gradations from normal to severely stressed, on the 150 employees.

The company said that subjects would be assessed through self-report, clinical interview, and cardiac rate patterns.

Medibio said that the first phase involved measurement of employee stress symptoms and the second phase would test its Unwind online stress-reduction training program.

Medibio fell one cent or 2.9 percent to 34 cents.

## GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 57,359,151 shares (12.06%) to 62,359,151 shares (13.11%).

The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said it acquired 5,000,000 shares for \$174,625 or an average price of 3.5 cents a share.

The company's website said it was listed on London's Alternative Investment Market.

The Crystal Amber Fund substantial shareholder notice was signed by Kevin Smith and Danny Felbabel as company secretary.

GI Dynamics was unchanged at 3.5 cents with 2.2 million shares traded.

## MEDLAB CLINICAL

Medlab chief executive officer Sean Hall says that he has increased his holding from 54,922,222 shares to 56,255,555 shares but has been diluted to 31.48 percent.

Mr Hall said that directly and through Comdrex No 229 Pty Ltd he had acquired 1,333,333 shares for \$400,000 or 30 cents a share in the recent rights issue which has raised \$4,396,947 so far of the underwritten \$5,361,150 (BD: Aug 15, 2016).

Medlab fell one cent or 2.5 percent to 38.5 cents.

## LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 24.7 percent from 7.3 cents on August 12 to 9.1 cents today August 17, 2016 and noted a significant increase in the trading volume. Living Cell closed up 0.9 cents or 12 percent at 8.4 cents with 3.9 million shares traded.

## CSL

CSL says Dr Tadataka 'Tachi' Yamada has been appointed a director effective from September 1, replacing John Akehurst who will retire on October 12, 2016.

CSL said that Dr Yamada was a US citizen, resident in Seattle, Washington and a venture partner at Frazier Healthcare Partners.

The company said that Dr Yamada was previously Takeda Pharmaceuticals chief medical and scientific officer and a director of the company.

CSL said that Dr Yamada had held executive positions, including president of the Bill and Melinda Gates Foundation Global Health Program and Glaxosmithkline's research and development chairman and was currently a director of Agilent Technologies, and the Clinton Health Access Initiative and a member of the Council of the National Academy of Medicine.

The company said that Dr Yamada was a fellow of London's Imperial College of Medicine, a master of the American College of Physicians and a fellow of the Royal College of Physicians.

## ACTINOPEN MEDICAL

Actinopen says it has received an offer from an unnamed Australian financial services licensee to buy all unmarketable parcels of shares at 6.45 cents a share.

Actinopen said that an unmarketable parcel was a holding with a market value of less than \$500 and would be any holding of 8,928 shares or fewer at 5.6 cents a share, the closing price on the record date of August 15, 2016.

The company said that about 515 of the company's 1,864 shareholders held unmarketable parcels, comprising about 0.34 percent of the shares on issue.

Actinopen said that it would organize payment of all the costs of sale for shareholders taking-up the offer free of brokerage, although tax consequences would remain the shareholder's responsibility.

Actinopen was up 0.3 cents or 5.1 percent to 6.2 cents.