



# Biotech Daily

Wednesday August 14, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: ALTERITY UP 15%; PHARMAXIS DOWN 11%**
- \* **CSL RECORD REVENUE UP 8% TO \$12.5b, PROFIT UP 11% TO \$2.8b**
- \* **OSPREY H1 REVENUE UP 54% TO \$2.7m, LOSS UP 5% TO \$12.6m**
- \* **MESOBLAST: INVESTIGATOR REMSTEMCEL-L FOR CHRONIC GVHD TRIAL**
- \* **NUHEARA REGISTERED AS NDIS HEARING EQUIPMENT PROVIDER**
- \* **MACH7 WINS 3 US IMAGING CONTRACTS WORTH \$500k**
- \* **BOD: HUMAN CELLS WITH MARIJUANA FOR AGEING**
- \* **BAKER BROTHERS TAKES 11% OF OPTHEA**
- \* **AUSTRALIAN ETHICAL DILUTED TO 4.99% OF IN IMMUTEP**
- \* **SUDA APPOINTS DR RICHARD FRANKLIN ANAGRELIDE DIRECTOR**
- \* **VIVAZOME APPOINTS DR DAVID HAYLOCK CSO**

## MARKET REPORT

The Australian stock market was up 0.42 percent on Wednesday August 14, with the ASX200 up 27.4 points to 6,595.9 points.

Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and two were untraded.

Alterity (Prana) was the best, up 0.4 cents or 15.4 percent to three cents, with 1,450,000 shares traded. CSL and Polynovo climbed more than six percent; Antisense was up 5.6 percent; Prescient improved 4.65 percent; Osprey was up 3.2 percent; Avita and Resmed rose more than two percent; Cynata and Genetic Signatures were up one percent or more; with Next Science, Paradigm and Pro Medicus up by less than one percent.

Pharmaxis led the falls, down 2.5 cents or 10.9 percent to 20.5 cents, with 1.4 million shares traded. Dimerix, Immuteq, Imugene, LBT and Medical Developments fell more than four percent; Telix lost 3.9 percent; Universal Biosensors and Volpara shed more than two percent; Amplia, Compumedics and Starpharma were down more than one percent; with Clinuvel, Mesoblast and Neuren down by less than one percent.

## [CSL](#)

CSL says that revenue for the year to June 30, 2019 was up 7.9 percent to \$US8,538.6 million (\$A12,574.8 million) with net profit after tax up 11.0 percent to \$US1,918.7 million (\$A2,825.7 million).

A CSL spokesperson told Biotech Daily that both revenue and profit were at record highs. CSL said that sales were up in all regions, with North American sales up 11 percent, European Union sales up nine percent, Asian Pacific sales up 10 percent and sales up 17 percent in the rest of the world.

In a media release CSL chief executive officer Paul Perreault said he was “pleased to report a robust result given it follows a very strong comparative period”.

Mr Perreault said the company’s immunoglobulin portfolio was performing “exceptionally well”, driven by its chronic inflammatory demyelinating polyneuropathy (CIDP) indication for Hizentra and Privigen in the US and Hizentra in Australia.

Mr Perreault said the company was progressing its CSL112 phase III trial, had enrolled its CSL312 phase II trial for hereditary angioedema (HAE) and had initiated its CSL964 phase II/III trial to prevent graft versus host disease (GvHD) with a1-antitrypsin (AAT).

The company said Privigen sales were up 23 percent, Hizentra sales improved 22 percent, Idelvion sales were up 40 percent and Aftyla sales rose 85 percent.

CSL said its Albumin sales grew 15 percent, with its China Albumin sales up 14 percent.

The company said its specialty products sales increased six percent, including Kcentra up 14 percent and Haegarda up 61 percent.

CSL said its Sequirus seasonal influenza vaccine sales were up 19 percent and sales of the influenza vaccine Fluad for people over 65 years “more than doubled”.

The company said it was named in the top 100 global diversity and inclusion index by Thomson Reuters, with 25,000 employees, a 13 percent increase from the previous year.

Mr Perreault said CSL’s plasma and recombinant products continued to be strong and it expected “to again outpace the market in growing plasma collections and plan to open around 40 new collection centres in 2020”.

Mr Perreault said the company would transition to a direct distribution model in China, which would have “a one-off financial effect on 2020 albumin sales” and it expected Sequirus to continue to perform well and deliver in line with prior guidance, benefiting from product differentiation and process improvement”.

CSL said it had opened its Melbourne-based Bio21 research facility, 30 new plasma collection centres in the US and implemented its enterprise resource planning systems globally.

The company said that a final unfranked dividend of \$US1.00 (\$A1.47) per share, up seven percent compared to the previous year, would be paid on October 11 to shareholders at the record date of September 11, 2019, following the unfranked interim dividend of 85 US cents per share (\$A1.25) paid on April 12, 2019.

The company said that its net tangible asset backing per share was up 47.9 percent from \$US5.03 to \$US7.44, with diluted earnings per share up 10.9 percent to \$US4.226.

CSL said that research and development spending increased 18.4 percent to \$US831.8 million compared to the previous year and was 9.7 percent of the total revenue.

The company said it had \$US657.8 million in cash and cash equivalents at June 30, 2019, compared to the previous corresponding period’s \$US814.7 million.

Mr Perreault said that the net profit after tax for 2019-’20 was expected to increase seven to 10 percent to \$US2,050 million to \$US2,110 million at constant currency, taking into account “the one-off financial headwind of transitioning to a new model of direct distribution in China”.

CSL climbed \$14.50 or 6.6 percent to \$234.00 with 1.6 million shares traded.

## OSPREY MEDICAL

Osprey says revenue for the six months to June 30, 2019 was up 54.2 percent to \$US1,820,403 (\$A2,682,026) with net loss after tax up 5.1 percent to \$US9,207,896 (\$A13,565,964).

Osprey said the increased revenue came from sales of its contrast dye minimization products and from four group purchasing organization contracts.

The company said that diluted loss per US share was down 20 percent to four US cents, net tangible assets per Chess depositary instrument (CDI) was down 42.9 percent to four US cents and it had cash and cash equivalents of \$US16,274,842 at June 30, 2019, compared to \$US23,333,804 at June 30, 2018.

Osprey was up 0.2 cents or 3.2 percent to 6.4 cents.

## MESOBLAST

Mesoblast says researchers at Duke University are planning a trial of remestemcel-L for paediatric chronic graft-versus-host-disease.

In May, Mesoblast said it filed the first part of a rolling biologics licence application submission to the US Food and Drug Administration for the use of remestemcel-L in children with steroid-refractory acute GvHD (BD: May 30, 2019).

Today, the company said that Prof Jerome Harris and Dr Joanne Kurtzberg would lead the study at the Durham, North Carolina-based Duke University Medical Centre.

A Mesoblast spokesperson told Biotech Daily the trial protocols were being finalized for an investigational new drug application to the US Food and Drug Administration.

The company said chronic graft-versus-host-disease manifested later than 100 days and occurred in 30 percent to 70 percent of bone marrow transplant patients.

Last year, Mesoblast said that 38 of 55 children (69%) in its open-label, phase III trial of remestemcel-L for acute graft versus host disease survived to 180 days; and 33 of the 38 children (87%), who responded to its mesenchymal stem cell treatment at day-28 were alive at day-100 with the treatments well-tolerated (BD: Sep 20, 2018).

Mesoblast fell half a cent or 0.3 percent to \$1.475.

## NUHEARA

Nuheara says it has been registered as a hearing equipment provider for the Australian National Disability Insurance Scheme, effective immediately.

Nuheara said its Iq buds hearing and sound filtering products would be available with National Disability Insurance Scheme (NDIS) approved funding to support people with autistic spectrum disorder.

The company said Australian autism peak body Amaze reported that people with autism made up 29 percent of NDIS participants and they often showed auditory processing difficulties in the form of an auditory processing disorder.

Nuheara said the University of Melbourne's Centre for Auditory Neuroscience provided a preliminary report on the use of its Iq buds Boost for autistic children.

The company said that "while subject numbers were small, there was a significant improvement in auditory attention obtained".

Nuheara chief executive officer Justin Miller said the company had "anecdotal evidence to suggest that Nuheara's products would support people on the autism spectrum".

"Being listed on the NDIS places Nuheara at the centre of hearing health care beyond mild hearing loss," Mr Miller said.

Nuheara was up 0.4 cents or 12.5 percent to 3.6 cents with 10.6 million shares traded.

## MACH7 TECHNOLOGIES

Mach7 says it has won \$500,000 in three new contracts with Colorado Imaging Associates, University of Washington Medicine and Sentara Halifax Regional Hospital. Mach7 said its platform could be used to provide a complete enterprise imaging strategy, to solve inter-operability issues in healthcare organizations and to take a modern approach to picture archiving and communication systems (PACSs).

The company said the Golden, Colorado-based Colorado Imaging Associates purchased its platform, the Seattle, Washington-based UW Medicine purchased a licence to expand its use of the platform and Sentara Halifax Regional Hospital contracted the company to migrate 700,000 studies from its PACS.

Mach7 was up five cents or 6.7 percent to 80 cents with 2.2 million shares traded.

## BOD AUSTRALIA

Bod says a study with the University of Technology Sydney shows that a family of human cell proteins provide an antioxidant protective effect on skin cells.

Bod said it applied the novel family of proteins to skin cells and found that they helped “to increase both their tolerance ( $p < 0.0001$ ) and recovery ( $p < 0.01$ ) to ultraviolet light, along with other sources of oxidative damage when overexpressed in mammalian cells”.

The company said additional experiments showed “increased levels of antioxidant activity ( $p < 0.01$ ), and cellular growth and metabolism ( $p < 0.5$ ,  $p < 0.01$ ), furthering the proteins’ cellular protective effects”.

The company did not publish the details of the study or the comparators.

Bod said the findings would allow it to develop a patent-protected, anti-ageing topical application and delivery system, use the protein as a delivery method for cannabidiol or hemp extracts and to develop ways in which the proteins could be used in topical skin creams.

Bod chief executive officer Jo Patterson said, “the results of this three-year collaboration provide Bod with a fantastic commercial opportunity in both the anti-aging market and cannabis markets, which are both rapidly growing and ever changing”.

“The company is in the position to develop a suite of products that utilise these novel proteins in combination with specific [cannabidiol] extracts and other cannabis compounds, allowing for increased optionality over its broader product suite,” Ms Patterson said.

“This will position Bod with an intellectual property-protected and patentable product suite building greater value for the total business,” Ms Patterson said.

Bod was up five cents or 9.6 percent to 57 cents.

## OPTHEA

Baker Brothers Advisors LP says it has increased its substantial shareholding in Opthea from 16,385,959 shares (8.13%) to 26,526,759 shares (10.6%).

The New York-based Baker Brothers said that between September 18, 2018 and August 12, 2019, it acquired 10,310,192 shares, with a single largest purchase of 4,584,977 shares for \$US8,676,563 (\$A12,844,364) or \$2.80 a share on August 12, 2019.

Opthea was unchanged at \$2.60 with 526,724 shares traded.

## IMMUTEP

Australian Ethical Investment says it has increased its holding in Immutep but diluted from 181,013,867 shares (5.06%) to 193,004,549 shares (4.99%).

The Sydney-based Australian Ethical said that on August 6, 2019 it bought 11,790,682 shares for \$251,804 or 2.1 cents a share and was diluted in the recent \$6 million one-for-11.8 entitlement offer at 2.1 cents a share (BD: Aug 6, 2019).

Immutep fell 0.1 cents or 4.55 percent to 2.1 cents with 2.8 million shares traded.

## SUDA PHARMACEUTICALS

Suda says it has appointed Dr Richard Franklin as project director to complete phase I studies of its anagrelide adjunctive oro-mucosal therapy for cancer.

Last year, Suda said it would develop a soluble version of Anagrelide that could be administered as an oral spray (BD: Jul 12, 2018).

Today, the company said Dr Franklin had more than 40 years' experience in pharmaceutical research and development and previously worked for Glaxo, Wyeth, Sterling Winthrop and Shire Pharmaceuticals.

Suda said Dr Franklin was previously the chairman and secretary of the European Drug Metabolism Discussion Group and the associate editor of the journal Xenobiotica.

The company said Dr Franklin was a member of its scientific advisory board.

Suda fell 0.1 cents or 20 percent to 0.4 cents with 18.5 million shares traded.

## VIVAZOME THERAPEUTICS

Vivazome says it has appointed Dr David Haylock as its chief scientific officer to lead the scientific and technical programs for an exosome therapy for ischemic conditions.

The Melbourne-based Vivazome said it was formed to develop and commercialize exosome-based therapies for debilitating and/or life-threatening disorders, with an initial focus on critical limb ischaemia.

The company said that exosomes were small particles released by cells and "a key effector in communication between cells".

Vivazome said that exosomes had "the potential to become an off-the-shelf medicine without the technical problems of cell therapies" and it aimed to develop a large-scale, manufacturing process.

The company said that Dr Haylock had experience in cell biology, cell therapies and operational management and had worked at the Commonwealth Scientific and Industrial Research Organisation, the Australian Stem Cell Centre, the Peter MacCallum Cancer Centre and Adelaide's Institute of Medical and Veterinary Science.

Vivazome said that Dr Haylock held a Bachelor of Applied Science from the South Australian Institute for Technology and Doctor of Philosophy from the University of Adelaide.

Vivazome is a private company.