



Biotech Daily

Wednesday February 12, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: AMPLIA UP 19%; ONCOSIL DOWN 10%**
- * **CSL RECORD H1 REVENUE UP 9% TO \$7.3b, PROFIT UP 7.5% TO \$1.85b**
- * **CSL ADJUVANT FOR QUEENSLAND UNI COVID-19 VACCINE**
- * **USCOM TELLS ASX: 'MATERIAL RISE IN CHINA ORDERS NOT MATERIAL'**
- * **NORTH STAR TO SUPPLY CLARITY COPPER-67**
- * **INVICTUS: US PATENT FOR TOCOTRIENOL DELIVERY**
- * **EXOPHARM: PLEXARIS, CEVARIS EXOSOMES 'SAFE' IN-VITRO**
- * **NOXOPHARM REQUESTS 'CAPITAL STRUCTURE' TRADING HALT**
- * **ALLAN GRAY REDUCES TO 13% OF IMPEDIMED**
- * **W WHITNEY GEORGE TAKES 27% OF RHINOMED**
- * **ONE FUNDS MANAGEMENT TAKES 6% OF BLUECHIIP**
- * **STARPHARMA APPOINTS DAVID MCINTYRE DIRECTOR**
- * **DOUG HUEY REPLACES PYC CEO DR ROHAN HOCKINGS, ON \$892k**
- * **RESPIRI RE-APPOINTS DR THOMAS DUTHY DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.47 percent on Wednesday February 12, 2020, with the ASX200 up 32.9 points to 7,088.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell and 11 traded unchanged.

Amplia (formerly Innate) was the best, up 1.4 cents or 19.2 percent to 8.7 cents with one million shares traded. Alterity (Prana), Ellex and Immutep climbed more than five percent; Impedimed and Uscom improved more than four percent; Proteomics was up 3.6 percent; Genetic Signatures and Universal Biosensors rose more than two percent; Next Science and Volpara were up more than one percent; with CSL, Mesoblast, Paradigm, Pro Medicus, Resmed and Starpharma up by less than one percent.

Yesterday's 7.9 percent best, Oncosil, led the falls, down two cents or 9.8 percent to 18.5 cents with 6.8 million shares traded. LBT lost 7.1 percent; Cyclopharm, Dimerix and Prescient were down six percent or more; Antisense fell 4.8 percent; Compumedics, Medical Developments and Neuren shed two percent or more; Cochlear, Clinuvel, Opthea and Polynovo were down more than one percent; with Kazia and Nanosonics down by less than one percent.

[CSL](#)

CSL's revenue for the six months to December 31, 2019 was up 9.0 percent to \$US4,910.6 million (\$A7,297.7 million) with net profit after tax up 7.5 percent to a record \$US1,248.0 million (\$A1,854.7 million).

CSL said that research and development expenditure increased 13.9 percent to \$US445.5 million for the six months to December 31, 2019 or 9.1 percent of total revenue, compared to 14.0 percent for the six months to December 31, 2018.

The company said that diluted earnings per share was up 6.9 percent to \$US2.74 and that it had cash and cash equivalents of \$US659.7 million at December 31, 2019 compared to \$US644.9 million at December 31, 2018.

CSL said the interim unfranked dividend of 95 US cents, was up 11.8 percent compared to the previous corresponding period and would be paid on April 9, with a record date of March 12, 2020.

CSL chief executive officer Paul Perreault said the company's results "reflect the focused execution of our strategy, robust demand for our differentiated medicines and a deep, inherent passion for meeting the evolving needs of our patients."

"Our largest franchise, the immunoglobulin portfolio, performed exceptionally well, with Privigen sales growing 28 percent and Hizentra sales up 37 percent," Mr Perreault said.

"Underpinning this growth has been continued strong patient demand together with an expanded label claim for both Privigen and Hizentra to now include chronic inflammatory demyelinating polyneuropathy, a debilitating neurological disorder," Mr Perreault said.

"Albumin sales grew well key markets with the exception of China, where we are transitioning to our new direct distribution model," Mr Perreault said.

"This transition has seen overall albumin sales decrease 33 percent, which is in line with guidance," Mr Perreault said.

"The China transition is progressing well and will improve our participation in the value chain as well as allowing us to now work directly with clinicians," Mr Perreault said.

"The availability of albumin to patients has not been impacted and reported sales are expected to return to a more normalized level [by June 30, 2021]," Mr Perreault said.

"Our haemophilia portfolio continues to evolve with strong growth in our recombinant haemophilia products, Afstyla and Idelvion, which grew 30 percent and 21 percent respectively," Mr Perreault said.

"We've worked hard with our specialty product Zemaira to regain patients and have grown sales by 31 percent," Mr Perreault said.

"Peri-operative bleeding products, which includes Kcentra, also performed well, with double-digit growth," Mr Perreault said.

"Overall specialty products growth, however, has been tempered by manufacturing capacity constraints in the production of Haegarda, following exceptionally robust patient demand since its launch," he said.

New capacity has now received regulatory approval, removing this supply constriction," Mr Perreault said.

"Our Seqirus influenza vaccines business executed well and delivered another strong performance in the first half, driven by sales of new and differentiated products Flucelvax and Fluad," Mr Perreault said.

Mr Perreault said the outlook for the year to June 30, 2020 was an expected net profit after tax of \$US2.11 billion to \$US2.17 billion, at constant currency or about 10 percent to 13 percent growth over the year to June 30, 2019.

He said that given the seasonal nature of the Seqirus business, the company expected to post a loss in the six months to June 30, 2020.

CSL was up \$2.52 or 0.8 percent to \$328.25 with 861,105 shares traded.

CSL

CSL says it is providing expertise and its influenza subsidiary Seqirus's MF59 adjuvant to the University of Queensland's coronavirus disease-19 (Covid-19) vaccine program.

CSL said that coronavirus was "quite different to influenza virus so it is not a core area of focus for CSL or Seqirus".

"However, we have investigated possible adjacencies in expertise, technologies and facilities that might be able to contribute to the global effort and ... we have partnered with the University of Queensland's COVID-19 vaccine development program", the company said.

CSL said it would provide technical expertise as well as a donation of Seqirus' adjuvant technology MF59, to the University's pre-clinical development program.

The company said that adjuvants were used in vaccines to build "a stronger immune response and to speed vaccine production and output".

CSL said that the Seqirus adjuvant technology had "a long history of use and a strong safety profile in both seasonal and pandemic influenza vaccines".

The company said that the University of Queensland would use the adjuvant to test a viral protein being developed with its molecular clamp technology.

"The University of Queensland's research program is just starting and it will be some months before the success of the program will be known," CSL said.

"In the pre-clinical development stage, this is a humanitarian effort, not a commercial one, and CSL is contributing its support to our partners due to the critical need of this public health emergency," the company said.

CSL said it continued "prioritize the safety and security of our employees in Wuhan and we are monitoring, every day, the health of our 600 employees in China".

CSL said it had donated RMB1 million (\$A213,365) to the China Red Cross in support of efforts to combat the epidemic.

USCOM

Uscom has told an ASX query that announcements describing a material increase in orders from China were not material because they had been foreshadowed.

The ASX cited the 59 percent price query of February 6, the announcement titled 'Material increase in Uscom 1A orders in China' on February 10 and 'Clarification - Material increase in Uscom 1A orders in China' on February 11, 2018, citing new orders in the first five weeks of 2020 and a 124 percent increase from 17 to 38 units in two months, and asked if the information was material and if not why not.

Uscom said its Appendix 4C quarterly report on January 23, 2019, reported a "...rush of new sales in the first week of January (\$400,000). Received orders and forecast sales for [the three months to March 31, 2020] indicate significant impending sales".

The company said that the February 10 announcement "disclosing a material increase in unit orders for the Uscom 1A device during the 'first five weeks of 2020' was therefore not information which had not previously been disclosed to the ASX".

"The statement was confirming the information provided on January 23, 2020 in its Appendix 4C that a 'rush of sales' had occurred and that Uscom's stated expectation that there were 'significant impending sales' was validated," Uscom said.

The company said it was aware of the information referred to by the ASX on the dates they were announced.

Uscom said it was complying with the Listing Rules and, in particular, Listing Rule 3.1.

Uscom recovered 1.5 cents or 4.05 percent to 38.5 cents with 3.5 million shares traded.

[CLARITY PHARMACEUTICALS](#)

Clarity says the Beloit, Wisconsin-based North Star Medical Technologies will supply copper-67, for use in its copper-based radio-pharmaceuticals for cancers.

North Star chief executive officer Stephen Merrick said that clinical development of copper-67 (Cu-67) based radio-pharmaceuticals “has been limited to date due to lack of stable chelators for Cu-isotopes and limitations in supply”.

“With Clarity Pharmaceuticals’ leading copper chelating technology and product pipeline advancing into a range of [diagnostic and therapeutic] clinical trials that use Cu-64 [and] Cu-67 pairing, industrialization of Cu-67 production is required,” Mr Merrick said. “North Star is addressing this need and advancing towards commercial-scale production.”

Clarity executive chairman Dr Alan Taylor said that North Star’s experience in the development and commercialization of radio-isotope technologies would help advance research and clinical development efforts and “having access to a reliable and scalable supply of Cu-67 in the US will enable us to apply our proprietary copper-chelating technology to a range of targeting agents for potential treatment of neuroblastoma, prostate, breast and ovarian cancers”.

Clarity is a public unlisted company.

[INVICTUS BIOPHARMA](#)

Invictus says the US Patent and Trademark Office has allowed a patent for the delivery of tocotrienols for the treatment or prevention of muscle soreness.

Invictus said the patent, titled ‘Transmucosal delivery of tocotrienols’, would provide commercial rights in the US until 2033.

The company said a divisional patent application covering other indications relevant to its drug development programs would be lodged shortly.

Invictus executive chairman Dr Glenn Tong said the US patent followed the recent European Union patent grant and was a “step forward for our patent protection strategy in the two largest markets for nutraceuticals and pharmaceuticals”, with corresponding patents granted in Australia, the EU, Japan, New Zealand, Singapore and South Africa. Invictus is a public unlisted company.

[EXOPHARM](#)

Exopharm says in-vitro tests have found its exosome products Plexaris and Cevaris safe and with notable activity compared to other medicines.

Exopharm said the Luxembourg-based Eurofins compared both products with 4,500 experimental and sold medicines and found the platelet-derived Plexaris and the adult stem cell-derived Cevaris exosomes showed activity when modulating cell adhesion molecules, major histo-compatibility complex class II receptors and protease inhibitor biomarkers associated with inflammatory, immunomodulatory and tissue remodelling.

The company said the tests also found Cevaris active in modulating extracellular proteins and protein biomarkers such as cytokines and chemokines.

Exopharm said the comparison of Plexaris and Cevaris with the database of 4,500 other medicines did not produce a significant match, suggesting both exosomes had different and distinct activities to existing drugs.

The company said the results might not translate to future testing in non-clinical or clinical trials, with the tests not reviewed by an external ethics committee or regulatory agency and not sufficient to replace the specific toxicology tests required to permit human trials.

Exopharm was up nine cents or 34.6 percent to 35 cents.

NOXOPHARM

Noxopharm has requested a trading halt pending an announcement relating to “an update on the company’s capital structure, including capital raising program”.

Trading will resume on February 14, 2020 or on an earlier announcement.

Noxopharm last traded at 22.5 cents.

IMPEDIMED

Allan Gray Australia says it has decreased its substantial holding in Impedimed from 75,110,704 shares (14.81%) to 68,550,246 shares (13.41%).

The Sydney-based Allan Gray said it bought and sold shares between September 2, 2019 and February 10, 2020 with the single largest sale 1,081,535 for \$147,907 or an average of 13.7 cents a share.

Impedimed was up half a cent or 4.55 percent to 11.5 cents.

RHINOMED

W Whitney George says he has increased his substantial shareholding in Rhinomed from 44,158,951 shares (26.09%) to 46,291,546 shares (27.36%).

The Carlsbad, California-based Mr George said that between December 18, 2019 and February 7, 2020 he acquired 2,132,595 shares for \$US253,678 (\$A376,803) or 11.9 US cents (about 17.7 Australian cents) a share.

Rhinomed was unchanged at 16 cents.

BLUECHIIP

Sydney’s One Funds Management says it has become a substantial shareholding in Bluechiip with 34,000,000 shares or 6.73 percent of the company.

One Funds Management said it acquired shares between September 10, 2018 and February 11, 2020, for \$2,596,269 or 7.6 cents a share, with the single largest purchase 21,186,441 shares on September 11, 2018 for 5.9 cents a share.

Bluechiip fell half a cent or 4.0 percent to 12 cents with 2.1 million shares traded.

STARPHARMA

Starpharma says it has appointed David McIntyre as a non-executive director, effective from March 1, 2020.

Starpharma said the US-based Mr McIntyre was currently the chief financial officer of Avita and a non-executive director of Redflex, and previously was the chief financial officer and chief operating officer at Heartware International.

The company said Mr McIntyre had been a partner at Apple Tree Partners for seven years, during which time was a director of several US biotechnology companies.

Starpharma said Mr McIntyre held a Bachelor of Laws from the University of Technology Sydney and a Master of Business Administration from the Durham, North Carolina-based Duke University.

Starpharma was up half a cent or 0.4 percent to \$1.13.

[PYC THERAPEUTICS, \(FORMERLY PHYLOGICA\)](#)

PYC says it has appointed Douglas Huey as chief executive officer replacing Dr Rohan Hockings, and starting on \$US600,000 (\$A891,805) a year.

PYC said Dr Hockings would continue as a director and chief strategy officer.

The company said that Mr Huey had been appointed chief executive officer and a director effective from yesterday, February 11, 2020, and would be based in Boston, Massachusetts.

PYC said the US move was “a major step ... as it progresses towards clinical drug development”.

The company said that Mr Huey was formerly a partner at the Perth office of McKinsey & Co, moving from the US to Australia in 2013 to develop the Perth McKinsey office.

PYC said that Mr Huey held a Master of Business Administration from the Evanston Illinois-based Kellogg School of Management.

The company said that Mr Huey’s base salary would be \$US600,000 a year plus US-based healthcare benefits and he would be issued 20,000,000 options exercisable at 6.3 cents each by February 28, 2023, with one third vesting on issue, one third vesting on February 28, 2021 and the balance on February 28, 2022.

PYC was unchanged at 6.2 cents.

[RESPIRI](#)

Respiri says it has reappointed Dr Thomas Duthy as a non-executive director, effective from February 11, 2020.

In 2018, Respiri said it had appointed Dr Duthy as a director, but a month later, along with chairman Mark Ziirszen and director Brendan Mason, he was replaced by Ross Blair-Holt and Prof Bruce Thompson (BD: May 31, Jun 14, Oct 24, Nov 27, 2018).

Yesterday, Prof Thompson resigned as a director (BD: Feb 11, 2020).

Today, Respiri said that Dr Duthy was formerly head of investor relations and corporate development at Sirtex Medical until its sale in 2018.

Respiri was up 0.2 cents or 2.4 percent to 8.5 cents.