



Biotech Daily

Tuesday August 15, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: STARPHARMA UP 13%; PHARMAXIS DOWN 12%**
- * **CSL REVENUE UP 26% TO \$20.5b; PROFIT DOWN 3% TO \$3.4b**
- * **COCHLEAR REVENUE UP 17.5% TO \$1.94b; PROFIT DOWN 4% TO \$300.6m**
- * **PRO MEDICUS REVENUE UP 34% TO \$125m; PROFIT UP 36.5% TO \$60.6m**
- * **VICTORIA, MODERNA OPEN mRNA HQ, RESEARCH CENTRE**
- * **OPTISCAN DEVELOPING REMOTE ACCESS MICROSCOPY**
- * **CHIMERIC CHM0301 'MORE RESISTANT, POTENT; IN-VITRO'**
- * **CLINUVEL: 'AFAMELANOTIDE REDUCES DNA PHOTO-DAMAGE'**
- * **ACTINOGEN: \$4.56m RIGHTS ISSUE SHORTFALL COMMITMENT**
- * **ALTERITY RECEIVES \$4.7m FEDERAL R&D TAX INCENTIVE**
- * **HERAMED 7.5m DIRECTOR OPTIONS EGM**
- * **BIOXYNE, CANXCHANGE MARIJUANA JOINT VENTURE**

MARKET REPORT

The Australian stock market was up 0.38 percent on Tuesday August 15, 2023, with the ASX200 up 28.0 points to 7,305.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and one was untraded. All three Big Caps rose.

Starpharma was the best, up two cents or 13.3 percent to 17 cents, with 4.9 million shares traded. Cochlear climbed 5.7 percent; Clinuvel, Micro-X, Polynovo, Pro Medicus and SDI improved more than four percent; Atomo, CSL, Immutep, Kazia and Neuren were up more than three percent; Antisense, Imugene and Telix rose two percent or more; Resmed was up 1.3 percent; with Volpara up by 0.7 percent.

Pharmaxis led the falls, down 0.6 cents or 12.0 percent to 4.4 cents, with two million shares traded. Actinogen and Amplia lost more than 10 percent; Medical Developments and Patrys were down more than five percent; 4D Medical, Impedimed, Mesoblast and Proteomics fell four percent or more; Nova Eye was down 3.85 percent; Avita, Nanosonics and Paradigm shed two percent or more; Genetic Signatures and Universal Biosensors were down more than one percent; with Cyclopharm down by 0.4 percent.

CSL

CSL says revenue for the year to June 30, 2023 was up 26.0 percent to \$US13,310,000,000 (\$A20,467,000,000) with net profit after tax down 2.7 percent to \$US2,194,000,000 (\$A3,374,000,000).

CSL chief executive officer Dr Paul McKenzie said results were “driven by strong performance across all our business”.

“While we have not been immune to inflation and currency headwinds, our focus on improving efficiencies across our global network of manufacturing sites has helped reduce the impact,” Dr McKenzie said. “Our CSL Behring business rebounded strongly, driven by exceptional growth in immunoglobulin sales and record plasma collections.”

The company said sales of Idelvion was up 13 percent, Kcentra increased 10 percent, and Zemaira rose 24 percent as supply returned, with immunoglobulin product sales up 21 percent, albumin sales up 11 percent to \$US1,109,000,000, haemophilia product sales were up eight percent and Seqirus seasonal influenza vaccine sales improved 30 percent. CSL said that the Behring division improved 12 percent to \$US9.3 billion, with Seqirus revenue up nine percent to \$US2.0 billion and its Vifor business was up about 14 percent to \$US2.0 billion following its acquisition on August 9, 2022.

The company said that a partly-franked dividend of \$US1.29 per share, up 9.3 percent from \$US1.18 (\$A1.68) the previous year, would be paid on October 4 to shareholders at the record date of September 12, 2023.

Dr McKenzie said the “strong growth in our immunoglobulins franchise is expected to continue following record plasma collections in [2022-'23]”.

“We have a number of initiatives underway to improve efficiencies which include a focus on optimizing plasma collection costs, improving manufacturing yields and bringing new products to market, all of which will support the medium-term recovery in CSL Behring’s gross margin,” Dr McKenzie said.

“The launch of Hemgenix in the US last quarter will continue to deliver this paradigm-shifting treatment to the haemophilia B community in the US and Europe in the year ahead,” Dr McKenzie said.

“We anticipate that CSL Seqirus will deliver another strong year driven by demand for its differentiated products,” Dr McKenzie said. “For CSL Vifor, we are focusing on unlocking the value and growth within this newly acquired business.”

“Supporting our medium-term outlook, we are bringing together our research and development capabilities into the one [research and development] organization,” Dr McKenzie said.

“We are also combining nephrology and transplant therapeutic areas and have a number of patient blood management initiatives underway that leverages the strengths of CSL Vifor and CSL Behring,” he said.

Dr McKenzie said revenue in the current financial year was expected to be about nine to 11 percent above the year to June 30, 2023 “at constant currency”, with underlying profit, in the range of about \$US2.9 billion to \$US3.0 billion “at constant currency”.

CSL said that net tangible asset backing per share was down 88.45 percent to \$US2.86, relating to its acquisition of Switzerland’s Vifor Pharma, with diluted earnings per share down 5.6 percent to \$US4.53.

CSL said research and development spending rose 6.8 percent to \$US1,235 million compared to the previous year and was 9.3 percent of the total revenue, compared to \$US1,156 million in the previous year which was 10.9 percent of the total revenue.

The company said it had \$US1,548,000,000 in cash and cash equivalents at June 30, 2023 compared to \$US10,436,000,000 at June 30, 2022.

CSL was up \$9.80 or 3.7 percent to \$272.80 with 1.1 million shares traded.

COCHLEAR

Cochlear says revenue for the year to June 30, 2023 was up 17.5 percent to \$1,936,100,000 with net profit after tax down 3.98 percent to \$300,600,000.

Cochlear said underlying net profit, excluding \$38.5 million in cloud computing-related expenses, was up 10.2 percent to \$305,200,000.

The company said cochlear implant unit sales increased 16 percent, driven by “market growth, improved clinical capacity, market share gains and Covid catch-up surgeries”.

Cochlear said “the successful launch of the Cochlear Nucleus 8 sound processor ... generated strong demand for cochlear implant systems and sound processor upgrades”.

The company said operating expenses increased by 20 percent with research and development expenditure up 16.2 percent to \$244.9 million or 12.65 percent of revenue compared to the previous year’s \$210.7 million or 12.8 percent of revenue.

Cochlear said sales of its hearing implants as well as services and sound processor upgrades both increased by 16 percent to \$1.13 billion and \$584.4 million, respectively, with revenue from its acoustics products including Osia 2 and Baha 6 for mixed hearing loss was up 19 percent to \$239,900,000.

The company said 40.3 percent of its revenue came from the Americas, with 29.9 percent from Europe, the Middle East and Africa, and 14.6 percent from the Asia-Pacific.

Cochlear said it expected underlying net profit for 2023-'24 to be between \$355 million and \$375 million, with expenditure to be about \$70 million to \$90 million.

“Cochlear implant trading conditions continue to be strong across most markets, with an improving trend in adult referral rates in many developed countries,” the company said.

“At this stage, we expect solid market growth rates to drive high single digit growth in our cochlear implant units for [2023-'24],” the company said. “We expect market share gains ... to stabilize and for there to be fewer Covid-related backlog surgeries.”

The company said its partly-franked dividend was up 20.7 percent to \$1.75 per share, with a record date of September 19 and a payment date of October 11, 2023.

Cochlear said diluted earnings per share rose 3.75 percent to \$4.561, with net tangible assets per share up 1.05 percent to \$19.867, and it had cash and cash equivalents of \$555.5 million at June 30, 2023 compared to \$629.3 million at June 30, 2022.

Cochlear was up \$13.26 or 5.7 percent to \$246.47 with 299,236 shares traded.

PRO MEDICUS

Pro Medicus says revenue for the year to June 30, 2023 was up 33.6 percent to \$124,900,000 with net profit after tax up 36.5 percent to \$60,648,000.

Pro Medicus said the increased profit was due to a 41.8 percent rise in sales of its Visage hospital picture archive and communications system in North America, with Australia up 9.4 percent, while Europe shed 12.2 percent due to a one-off receipt the previous year.

The company said it signed seven contracts and renewals worth at least \$104 million over eight years, including with the University of Florida and the University of Washington.

Pro Medicus chief executive officer Dr Sam Hupert said “exponentially larger data sets, the transition to [the internet] cloud and the acute global shortage of radiologists, creates demands that are uniquely satisfied by our Visage technology”.

Pro Medicus said that a fully-franked dividend of 17.0 cents a share for holders on the record date of September 7, would be paid on September 28, 2023.

The company said diluted earnings per share up 36.5 percent to 58.0 cents for the year to June 30, 2023, with net tangible assets per share up 64.8 percent to 89 cents, and it had cash of \$91,248,000 at June 30, 2023 compared to \$63,656,000 at June 30, 2022.

Pro Medicus was up \$2.89 or 4.15 percent to \$72.51 with 314,930 shares traded.

VICTORIA GOVERNMENT, MODERNA AUSTRALIA

The Victoria Government says Moderna has opened its regional research centre and headquarters in Melbourne.

A media release from Victoria Minister for Industry and Innovation Ben Carroll said that he launched Moderna's Regional Research Centre for Respiratory Medicines and Tropical Diseases, which would "boost Victoria's mRNA industry".

The media release said that the regional centre was adjacent to Moderna's Australia, New Zealand, South-East Asia and Oceania headquarters.

The State Government said the Moderna Melbourne headquarters was a base to partner with Victoria's medical research institutes and clinical trial networks "ensuring Victorians will be some of the first people in the world to trial new mRNA medicines for a range of health conditions".

The Victoria Government said that the first collaboration for the Moderna Regional Research Centre for Respiratory Medicines and Tropical Diseases was a \$3 million quantitative pharmacology accelerator with the Monash Institute of Pharmaceutical Sciences (MIPS) in Parkville.

The Government said that the Monash-Moderna quantitative pharmacology accelerator would "help fast-track the development of mRNA medicines for diseases by using advanced computer models to predict the effects of treatments ... [and was the] first of many collaborations with Victorian research institutes as part of Moderna's investment in Victoria through their Asia Pacific Regional Research Centre".

The media release said that Moderna's mRNA Vaccine manufacturing facility in Clayton was under construction and when finished would be able to produce 100 million vaccine doses a year.

Moderna Asia-Pacific Regional Research Centre for Respiratory Medicines and Tropical Diseases director Dr Craig Rayner said that "by being embedded within a world-leading research and clinician community, we see huge potential in being able to innovate and accelerate life-changing mRNA medicines to patients, together".

OPTISCAN IMAGING

Optiscan says its remote access, single-cell imaging microscope has passed the proof-of-concept stage of development and expects it to be completed by the end of 2024.

Optiscan said it had partnered with the Mississauga, Ontario-based ProLucid Technologies to develop the technology, enabling remote access for pathologists to undertake virtual biopsy assessments.

Optiscan managing-director Dr Camile Farah said "the current conventional histopathology or physical biopsy approach is time-consuming for health providers, uncomfortable for patients and operationally challenging for anyone living in rural and remote areas".

"The combination of a high-performance, cloud-based tele-pathology platform integrated into our slide-free, biopsy-free, single-cell imaging technology, presents a unique opportunity to establish a new standard of digital pathology across the world," he said.

"We believe our telepathology platform will mark a game-changing moment in digital pathology," Dr Farah said.

"The platform will bring significant value to patients residing in rural or remote settings, while granting health systems the ability to access pathology expertise from anywhere in the world from any location including the operating theatre for real-time consultations between surgeons and pathologists," Dr Farah said.

Optiscan was up 0.2 cents or 2.7 percent to 7.7 cents.

CHIMERIC THERAPEUTICS

Chimeric says in-vitro data has shown CHM0301 for acute myeloid leukemia and colorectal cancer to be more resistant and potent than its previous CHM0201 cells. Chimeric said the CHM0301 “armored natural killer” cells built on the foundation of CHM0201 but were designed to overcome immune-suppressive tumor environments, in particular the immune-suppressant transforming growth factor-beta (TGFB) receptor inhibitor.

The company said that, compared to CHM0201, CHM0301 was more than three times more resistant to suppression by TGFB and up to 80 percent more potent in the presence of TGFB.

Chimeric said CHM0301 was 25 percent more potent in the absence of TGFB, as well. The company said it would evaluate CHM0301 in combination with Vactosertib, an oral TGFB receptor inhibitor.

Chimeric was unchanged at 3.8 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says the second set of results from its nine-patient trial of afamelanotide, the active ingredient of Scenesse, shows it reduces DNA photo-damage.

In February, the company said its nine-patient trial of 16mg afamelanotide showed it reduces skin damage, ultra- violet light-erythema response, increases pigmentation and supports DNA repair (BD: Feb 2, 2023).

At that time, Clinuvel said the trial showed afamelanotide was well tolerated, but two patients reported headaches and one had “mild nausea”.

Today, Clinuvel said biopsies of irradiated skin showed that DNA photo-damage expressed as cyclobutane pyrimidine dimers was significantly reduced at 15 minutes, 24 hours and 48 hours following afamelanotide treatment ($p < 0.01$).

The company said the results complemented the previous results that found UV-erythema damage had been reduced ($p = 0.018$), as well as previous studies showing melanin density significantly increased ($p < 0.05$).

Clinuvel head of clinical operations Dr Pilar Bilbao said it was “widely accepted that decreasing DNA photoproducts leads to a reduced risk and development of skin cancers, and we are working to evaluate these effects in high-risk populations”.

“These data not only support our clinical work to pursue a marketing authorization for the use of afamelanotide in [xeroderma Pigmentosa] patients, who are at high risk of developing multiple skin cancers per year and are left to lead an isolated life, but also for our photo-cosmetic product lines,” Dr Bilbao said.

Clinuvel was up 86 cents or 4.4 percent to \$20.32 with 74,910 shares traded.

ACTINOGEN MEDICAL

Actinogen says it has “binding commitments” of \$4.56 million for any shortfall for its rights issue from Defender Asset Management and McFarlane Cameron.

Earlier this month, Actinogen said it hoped to raise about \$10 million through a one-for-4.54, non-renounceable rights offer at 2.5 cents a share (BD: Aug 2, 2023).

Actinogen said the rights issue had a record date of August 14, would open on August 17 and close on September 4, 2023.

Actinogen fell 0.3 cents or 10.3 percent to 2.6 cents.

ALTERITY THERAPEUTICS

Alterity says it has received \$4,742,578 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Alterity said that incentive related to research and development expenditure for the year to June 30, 2022.

Alterity was unchanged at 0.7 cents.

HERAMED

Heramed says its shareholders will vote to issue director Ronald Weinberger 7,500,000 options, exercisable at 9.75 cents each by December 31, 2025.

Heramed said the options would vest in five tranches of 1,500,000 each, pending Dr Weinberger meeting a series of specified vesting conditions.

The company said the exercise price was a 50 percent premium to the closing share price prior to the "commencement date".

Heramed said shareholders would also vote to ratify placement shares and options, and the approval of broker options.

The meeting will be held at Automic group, Level 5, 126 Phillip Street, Sydney, on September 19, 2023 at 10.30am (AEST).

Heramed was unchanged at 7.3 cents.

BIOXYNE

Bioxyne says subsidiary Breathe Life Sciences has a joint venture with Canxchange to launch an artificial intelligence, business-to-business, online marijuana marketplace.

In May, Bioxyne said it had acquired the Gold Coast, Queensland-based Breathe Life Science (BD: May 22, 2023).

Today, the company said that London's Canxchange was a business-to-business marijuana platform in Europe that provided digital exchange venues, payment, compliance and data services.

Bioxyne said it expected the platform to be completed by the end of 2023 to facilitate wholesale trading between licenced buyers, sellers, cultivators and manufacturers.

Bioxyne did not disclose the commercial terms of the agreement.

Bioxyne was unchanged at 1.5 cents.