Biotech Daily

Tuesday August 13, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: SYNTARA UP 7%; ACTINOGEN DOWN 13%**

*** CSL REVENUE UP 20% TO $22.5b; PROFIT UP 20% TO $2.6b**

*** LTR, APTAR SPONTAN CO-DEVELOPMENT DEAL**

*** IMRICOR WITHDRAWS VISION-MR TGA FILE FOR 2nd GENERATION**

*** ANTERIS TO REDOMICILE TO US, NASDAQ LISTING**

*** HYDRIX REDUCES AVERTIX HOLDING VALUE TO $140k**

*** CHIMERIC TAKES $1.6m ENDPOINTS RDTI LOAN**

*** ARGENT (MGC) REQUESTS 'OFFICIAL LIST REMOVAL' HALT**

*** PLATINUM REDUCES TO 12.9% OF AMPLIA**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 86%**

*** CSL APPOINTS ELAINE SORG DIRECTOR**

*** PROTEOMICS LOSES DIRECTOR DR ROBYN ELLIOT**

MARKET REPORT

The Australian stock market was up 0.17 percent on Tuesday August 13, 2024, with the ASX200 up 13.1 points to 7,826.8 points. Ten of the Biotech Daily Top 40 companies were up, 23 fell, six traded unchanged and one was untraded.

Syntara was the best, up 0.2 cents or 6.7 percent to 3.2 cents, with 2.8 million shares traded. Atomo climbed five percent; Medical Developments improved 4.6 percent; Amplia was up 3.85 percent; Emvision and Pro Medicus rose more than two percent; Genetic Signatures, Imugene and Prescient improved more than one percent; with Clarity and Cochlear up by less than one percent.

Actinogen led the falls for the second day in a row, down 0.4 cents or 12.9 percent to 2.7 cents, with 50.2 million shares traded. Aroa lost 10.3 percent; Compumedics shed 8.1 percent; Resonance retreated 6.25 percent; Nanosonics was down 5.4 percent; Alcidion, CSL, Curvebeam, Dimerix, Nova Eye, Paradigm and Starpharma fell four percent or more; Avita was down 3.7 percent; Cynata, Medadvisor and Proteomics shed more than two percent; 4D Medical, Clinuvel, Immutep, Mesoblast, Micro-X, Neuren and SDI were down by one percent or more; with Resmed and Telix down by less than one percent.

CSL

CSL says revenue for the year to June 30, 2024 rose 11.2 percent to a record $US14,800,000,000 ($A22,492,000,000) with net profit after tax up 20.4 percent to a record $US2,642,000,000 ($A4,015,000,000).

CSL chief executive officer Dr Paul McKenzie said the results were “driven by an exceptional performance across CSL Behring’s portfolio, especially immunoglobulins”.

The company said the Behring division improved 15.0 percent to $US10.61 billion, with Seqirus revenue up 4.8 percent to $US2.1 billion and its Vifor business up about 3.8 percent to $US2.1 billion following its acquisition on August 9, 2022 (BD Aug 2, 2022).

CSL said its Behring business’ gross margin recovery to pre-Covid-19 pandemic levels was underway through a reduction in cost per litre of plasma by “optimizing donor experience, improving centre productivity and innovation, including through the rollout program for the [Terumo] Rika plasmapheresis technology and individual nomograms”.

“Underlying demand for [immune-globulins] continues to be robust across all the core indications”, Dr McKenzie said, including primary and secondary immune-deficiencies and chronic inflammatory demyelinating polyneuropathy.

CSL said sales of immune-globulin products Privigen and Intragam rose 21 percent, sub-cutaneous immune-globulin Hizentra was up 19 percent, haemophilia product Idelvion rose 10 percent, with Kcentra and Haegarda sales up five and 12 percent, respectively.

“We are under no illusions, there is still much more to do, but we are encouraged by the progress to date and will be working hard to continue this momentum,” Dr McKenzie said.

Dr McKenzie said CSL Seqirus “outperformed the market, with revenue growth of four percent at constant currency”, driven by sales of its Fluad flu vaccine increasing 14 percent to more than $1 billion for the first time and “in an evolving iron market” CSL Vifor had continued with “robust iron growth”.

The company said an unfranked dividend of $US1.45 per share, up 12.4 percent from $US1.29 the previous year, would be paid on October 2 to shareholders at the record date of September 10, 2024.

Dr McKenzie said during the year the first patients were dosed with the company’s gene therapy Hemgenix for haemophilia B patients, it received Japanese regulatory approval for its Kostaive “world’s first” self-amplifying mRNA Covid-19 vaccine and it filed US and European regulatory approvals for its garadacimab monoclonal antibody for angioedema.

Dr McKenzie said about the commercial launch of Hemgenix that “while the transition from referrals to administrations has been slower than we anticipated, largely due to the fragmented US healthcare system, we continue to experience an increasing rate of referrals, [and] these will result in new administrations in fiscal year 2025”.

Dr McKenzie said revenue for the year to June 30, 2025 was expected to be about five-to-seven percent above 2023-’24 “at constant currency”, with underlying profit up about 10 to 13 percent to between $US3.2 billion to $US3.3 billion “at constant currency”.

“Over the medium term, CSL is in a strong position to continue to deliver annualized double-digit earnings growth,” Dr McKenzie said.

CSL said that net tangible asset backing per share was down 121.3 percent to $US6.33, with diluted earnings per share down 20.3 percent to $US5.45.

CSL said research and development spending rose 12.8 percent to $US1,428 million or 9.6 percent of revenue, compared to $US1,269 million or 9.5 percent of revenue in 2023. Last year, the company said research and development expenditure was $US1,235 million, or 9.3 percent of total revenue (BD: Aug 15, 2023).

CSL said it had $US1,657,000,000 in cash and cash equivalents at June 30, 2024 compared to $US1,548,000,000 at June 30, 2023.

CSL

LTR PHARMA

LTR says the Chicago, Illinois-based Aptar Pharma will co-develop and commercialize its Spontan nasal spray for erectile dysfunction.
LTR said the primary goal was to commercialize Spontan nasal spray formulation of vardenafil, marketed as Levitra “in the US and other key markets”.
The company said Aptar Pharma operated “in drug delivery systems, services and active material science solutions [who had] supported numerous market authorization holders in obtaining their combination drug-device product approvals incorporating Aptar’s nasal delivery systems from regulatory agencies”.
LTR said the agreement would combine its pharmaceutical development capabilities with Aptar Pharma’s nasal spray technology, and that an expedited application for Spontan would be filed with the US Food and Drug Administration.
The company said it would have access to Aptar Pharma’s “comprehensive range of regulatory, analytical testing, and human factor services, which will considerably strengthen the FDA application process for Spontan”.
LTR did not disclose the commercial terms of the agreement.
LTR executive chair Lee Rodne said the agreement de-risked the FDA application and increased the profile of the company as a long-term partner of Aptar Pharma, which “may create opportunities for other products with alternative indications in future”.
LTR

IMRICOR MEDICAL SYSTEMS

Imricor says it has withdrawn its Australian Therapeutic Goods Administration application for its first-generation vision-magnetic resonance (MR) cardiac ablation catheter.
Imricor said it had withdrawn the application to complete the ‘Visibl-AFL’ atrial flutter trial, which would support US Food and Drug Administration approval of the second-generation ablation catheter, and it would “potentially subsequently submit to TGA for approval of the [generation] two catheter”.
Earlier this year, the company said it had approval for an up-to 91-patient, ‘Visabl-AFL’ study of its Vision-MR cardiac ablation catheter and irrigation pump products at sites in the US, France and Switzerland (BD: Jan 21, Mar 8, 2024).
Today, Imricor said it “did not anticipate a material impact on mid-term or long-term revenue potential”.
Imricor managing-director Steve Wedan said the company’s plan was “to sunset the manufacturing of the first-generation Vision-MR ablation catheter as soon as the [generation] two catheter is approved in Europe and the Middle East”.
“The [generation] two catheter has already received its [Conformité Européenne] CE mark device certificate in Europe under the new more stringent medical device regulations, and we are only awaiting the next in-house audit of our quality system to expand the scope of our manufacturing site certificate,” Mr Wedan said.
“Given the timing, [it] makes more sense to wait a few months, complete the Visabl-AFL trial, and possibly submit the [generation] two catheter to TGA alongside our submission for FDA approval,” Mr Wedan said. “That way, Australian doctors would not find themselves one generation behind, and we would not need to continue manufacturing the first-generation catheter only for Australia.”
Mr Wedan said that Australia was not material for revenue but wanted to bring the benefits of magnetic resonance imaging-guided ablations to Australia.
“Imricor has regulatory approval in New Zealand,” Mr Wedan said.
Imricor

ANTERIS TECHNOLOGIES

Anteris says it intends to redomicile to the US, list on the Nasdaq via the Delaware-based Anteris Technologies Global Corp and remain on the ASX Chess depository interests.
Anteris said the US holding company Anteris Technologies Global Corp expected to raise between about $US75 million ($A114 million) and $US100 million ($167 million) in an initial public offer of shares, which was expected to be underwritten, to list on the Nasdaq, with a secondary listing of Chess depository interests (CDI) to remain on the ASX.
The company said the actual sum to be raised, as well as the issue price, and any underwriting agreement was “yet to be determined and will depend on several factors”.
Anteris said that listing on the Nasdaq would provide access to US investors, increased its “global profile”, improve its attractiveness as a potential target for change of control transactions, create licencing, distribution or joint venture partnerships and reduce costs given a significant portion of its business was already located in the US.
The company said the funds raised in the initial public offer would be used to develop its Duravr transcatheter heart valve and an FDA trial of the device for severe aortic stenosis.
Anteris said all shares in the company would be transferred to the holding company Anteris Technologies Global Corp in exchange for one holding company share or CDI.
The company said the board “unanimously” recommended shareholders voted in favor of the scheme, which was subject to shareholder approval and the successful completion of the initial public offer as well as certain regulatory and court approvals.
Anteris

HYDRIX

Hydrix says it has reduced the value of its investment in Avertix Medical Inc from about $1,890,000 to $140,000, bringing the value of its total investment portfolio to $3,410,000.
Last year, Hydrix said that Angel Medical would merge with Bioplus Acquisition to become Avertix Medical, valued at $US195 million and its one million Angel shares would be about 29 percent of the merged company; and later, it said that Avertix Medical had applied to be listed on the Nasdaq (BD: May 4, 16, 2023).
In Ocotber, the company said Avertix and Bioplus Acquisition Corp had terminated their proposed merger and withdrawn their Nasdaq listing (BD: Oct 5, 2023).
Today, Hydrix said it held 10,000 shares in Avertix Medical and that it was advised that on August 10, 2024 Avertix completed a series C capital raise, which included a 100-to-one reverse stock split, which reset the stock price to $US9.27 ($A14.00) a share.
Hydrix executive chair Gavin Coote said the company was “disappointed by the impact of the write-down and look forward to Avertix, in due course, generating strong revenues to support a significant revaluation via a liquidity event”.
Hydrix

CHIMERIC THERAPEUTICS

Chimeric says it has a $1,562,000 loan from Endpoints Capital against the expected receipt of its research and development tax incentive for the year to June 30, 2024.
Chimeric said the loan provided it with early access to a portion of its expected Federal Government Research and Development Tax Incentive, which it expects to receive form the Australian Taxation Office by December 31, 2024.
The company said repayment was timed to follow the receipt of its incentive, with “interest charged at a commercial rate”.
Chimeric

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent has requested a trading halt “pending the release of an announcement concerning an application to be removed from the official list:”.
Trading will resume on August 15, 2024, or on an earlier announcement.
Argent last traded at 28.5 cents.

AMPLIA THERAPEUTICS

Sydney’s Platinum Investment Management Ltd says it has reduced its substantial shareholding in Amplia from 39,501,232 shares (14.54%) to 35,337,132 shares (12.89%).
Platinum said it sold the shares between July 3 and August 9, 2024, with the single largest sale of 1,869,260 shares on August 9 for $262,142, or 14.0 cents a share.
Amplia

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial shareholding from 95,468,379 shares (79.82%) to 102,843,318 shares (85.98%).
In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at $478,444; and later, filed his bidder’s statement (BD: May 27, Jun 20, 2024).
Yesterday, Allegra said all outstanding conditions had been met and its acquisition was “unconditional”, with shareholders to be paid within 10 days (BD: Aug 9, 12, 2024).
Today, Dr Hartnell said that he acquired the shares “as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024”.
Allegra was in a suspension and last traded at 2.9 cents.

CSL

CSL says it has appointed Elaine Sorg as an independent, non-executive director, effective from September 1, 2024.
CSL said Ms Sorg had more than 35 years of experience and prior to her retirement in 2023 had been head of Abbvie US commercial operations, had worked for Eli Lilly and was currently on the dean’s advisory council at West Lafayette, Indiana’s Purdue University School of Pharmacy and a senior advisor for Boston Consulting Group.
The company said Ms Sorg held a Bachelor of Science from Purdue University.
CSL

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says non-executive director Dr Robyn Elliot has resigned “due to personal commitments and following her retirement from CSL” effective from today.
In 2021, Proteomics said it appointed Dr Elliott as a director (BD: Nov 16, 2021).
The company said it was recruiting additional board and management to support its commercialization initiatives.
Proteomics