Biotech Daily

Tuesday February 13, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PARADIGM UP 9%; STARPHARMA DOWN 10%**

*** CSL RECORD H1 REVENUE UP 12% TO $12b, PROFIT UP 17% TO $3b**

*** IMMURON RECORD $2.7m TRAVELAN SALES**

*** OPTISCAN RECEIVES $3m FEDERAL INDUSTRY GRANT**

*** ORTHOCELL FILES SINGAPORE CELGRO-REMPLIR APPLICATION**

*** NEUROTECH MARIJUANA NTI164 AUTISM TRIAL EXTENSION**

*** NOXOPHARM EXTENDS HUDSON INSTITUTE AGREEMENT**

*** MGC 'ARGENT BIOPHARMA' NAME CHANGE EGM**

*** CURVEBEAM TO RELEASE 13m ASX ESCROW SHARES**

*** W WHITNEY GEORGE TAKES 44% OF RHINOMED**

*** ROBERT IERVASI REPLACES VITURA CHAIR DR MARCIA WALKER**

MARKET REPORT

The Australian stock market fell 0.15 percent on Tuesday February 13, 2024, with the ASX200 down 11.3 points to 7,603.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and one was untraded.

Paradigm was the best, up three cents or 8.6 percent to 38 cents, with 470,545 shares traded. Amplia climbed 6.8 percent; Actinogen and Impedimed improved more than five percent; Atomo, Mesoblast and Universal Biosensors were up more than three percent; 4D Medical and Genetic Signatures rose more than two percent; Clinuvel, Emvision, Neuren, Next Science, Orthocell and Polynovo were up one percent or more; with Cochlear, Medical Developments and SDI up by less than one percent.

Starpharma led the falls, down 1.5 cents or 10 percent to 13.5 cents, with 979,892 shares traded. Syntara (Pharmaxis) lost 8.3 percent; Compumedics was down 5.2 percent; Avita and Imugene fell more than four percent; Pro Medicus was down 3.2 percent; CSL, Cyclopharm and Immutep shed more than two percent; Clarity and Percheron (Antisense) were down more than one percent; with Nanosonics, Resmed, Telix and Volpara down by less than one percent.

CSL

CSL says record revenue for the six months to December 31, 2023 was up 12.1 percent to $US8,053,000,000 ($A12,332,911,000), with record net profit after tax up 17.1 percent to $US1,920,000,000 ($A2,940,418,000).

CSL said that research and development expenditure increased 16.2 percent to $US670 million for the six months to December 31, 2023, or 8.32 percent of total revenue, compared to 8.03 percent for the six months to December 31, 2022.

The company said an interim unfranked dividend up 11.2 percent to $US1.19, would be paid on April 3, for a record date of March 12, 2024.

CSL said diluted earnings per share rose 16.7 percent to $US3.92 and that it had cash and cash equivalents of $US1,017,000,000 at December 31, 2023 compared to $US1,507,900,000 at December 31, 2022.

At the company's investor briefing, CSL managing-director Paul McKenzie said "some of the late-stage pipeline assets did not meet their desired clinical outcomes, a risk inherent in research development pursuits".

Yesterday, CSL said its 18,200-patient, phase III trial of CSL112 to reduce the risk of major adverse cardiovascular events following a heart attack did not meet its primary endpoint (BD: Feb 12, 2024).

"Some of our existing portfolio is facing commercial and regulatory headwinds" including CSL Vifor's intravenous Ferinject for iron deficiency anaemia and Korsuva for pruritus associated with chronic kidney disease.

"These collective dynamics have dampened our near-term financial growth expectations for CSL Vifor," Mr McKenzie said.

CSL head of research and development Bill Mezzanotte said "the study did not meet the threshold for statistical significance".

"However, we do plan to discuss the results with major health authorities and to conduct numerous additional analyses to better understand the data and then determine any next steps in development," Mr Mezzanotte said.

CSL fell a further $7.99 or 2.75 percent to $282.25 with 1.3 million shares traded.

IMMURON

Immuron says it has record Travelan sales in the seven months to January 31, 2024 of $2.7 million, compared to the previous record of $2.5 million for the year to June 30, 2020.

In 2020, Immuron said revenue for the year to June 30, 2020 was up 5.5 percent to $2,518,566 with net loss after tax down 37.1 percent to $2,927,206 (BD: Sep 1, 2020).

Last year, Immuron said its revenue for the year to June 30, 2023 was $1,805,000, primarily from Travelan sales.

Today, the company said Australian sales of its oral Travelan cow colostrum hyperimmune product for travellers' diarrhoea was up to $2.1 million compared to $300,000 in the previous corresponding period.

Immuron said that US sales had doubled to $600,000 for the seven months to January 31, 2024 compared to $300,000 in the prior corresponding period.

Immuron chief commercial officer Flavio Palumbo said the company was "excited by the strong sales results on Travelan".

"Immuron's investment to drive awareness of the Travelan brand has seen strong sales results in Australia over the summer peak travel period," Mr Palumbo said. "We hope to get similar growth of the brand as we increase our investment and distribution in North America during the spring [and] summer vacation peak period."

Immuron was up 0.4 cents or 5.4 percent to 7.8 cents.

OPTISCAN IMAGING

Optiscan says it has received $3 million from the Federal Government's Department of Industry, Science and resources to develop its gastrointestinal endo-microscope.
Optiscan said the funds were part of the Cooperative Research Centres Projects grants announced by Minister for Industry and Science Ed Husic, and that the project was worth a total of $9,236,713.
The company said the project would be led by chief technology officer Dr Sanchitha Fernando and was in collaboration with the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Hydrix and Design & Industry.
Optiscan said the project would develop a "miniature digital microscopy probe that can fit biopsy channels of most endoscopes and provide real-time, slide-free images with sub-cellular resolution".
The company said the technology would use an artificial intelligence engine to detect and analyze cancerous and precancerous cells and would allow clinicians to conduct real-time endomicroscopy examinations and medically intervene if necessary.
Optiscan said the system would "significantly increase the changes of successful treatment and improve the prognosis for patients".
The company said once completed, the endo-microscope would be clinically tested and validated by the University Medical Center Mainz Germany's Prof Ralf Kiesslich who was involved with the development of its first gastrointestinal endo-microscope platform.
Optiscan managing-director Dr Camile Farah said the device would "open new opportunities in functional gastrointestinal imaging for conditions such as irritable bowel syndrome, Crohn's disease and ulcerative colitis, in addition to diagnosis and surgical management of gastrointestinal cancers and precancerous polyps".
"We are delighted to be the recipients of this competitive funding from the Department of Industry, Science and Resources which will turbo charge our development efforts and accelerate completion of our second-generation [gastro-intestinal product]," Dr Farah said.
Optiscan was up 0.2 cents or 2.1 percent to 9.9 cents.

ORTHOCELL

Orthocell says it has filed an application to the Health Services Authority of Singapore to market and sell its Celgro-based Remplir for peripheral nerve repair surgeries.
Orthocell said Remplir was generating revenue in Australia and pending application for use in the US, with Singapore expected to be the third country in which Remplir was available for sale.
The company said the US approvals process had progressed "according to plan with the Remplir 510k regulatory study on track for completion and data read out [by October 2024], with US regulatory application on track for submission in [2025] and approval expected shortly thereafter".
Orthocell said more than 100 orthopaedic and plastic surgeons were using Remplir for facial to upper and lower limb nerve surgery.
Orthocell managing-director Paul Anderson said applying with the Singapore authorities was "another significant milestone in our expansion strategy".
"Singapore is an important market and a stepping stone to the very large and attractive [Association of Southeast Asian Nations] targets", Mr Anderson said.
"Once approved, it will be the third country in which Remplir is available for sale, with US regulatory application, a key focus of the company, on track for submission [this year]," Mr Anderson said.
Orthocell was up half a cent or 1.3 percent to 39 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has ethics approval to extend its phase I/II trial of the marijuana-based NTI164 for autism spectrum disorder by another 52 weeks.

Last year, Neurotech said it had ethics committee approval for 11 paediatric patients in its phase I/II trial of NTI164 for autism spectrum disorder to continue treatment beyond the 18-month trial period under compassionate use (BD: May 31, 2023).

Today, Neurotech said the extension was "based on requests from the company's lead investigator, patients and their caregivers, to continue to extend the duration of treatment for these patients".

Neurotech executive director Dr Thomas Duthy said the company was focused on "completing the current phase II/III autism spectrum disorder trial and remain on track to report the results … [by July]".

Neurotech fell half a cent or 5.15 percent to 9.2 cents with 2.55 million shares traded.

NOXOPHARM

Noxopharm says it has extended its Sofra and Sof-skn research and development partnership with the Hudson Institute of Medical Research for one year.

Last year, Noxopharm said it had selected a pre-clinical, lead candidate based on mRNA technology as part of its Sofra pre-clinical platform (BD: Mar 28, 2023).

According to the company's website, it had licenced a technology from Melbourne's Hudson Institute of Medical Research to develop the Sofra technology platform, based on short nucleic acid sequences, known as oligo-nucleotides.

Today, Noxopharm said the partnership and in-licenced technology were "key components" of its Sofra platform, which included its Sof-Vac mRNA vaccine enhancer and Sof-skn topical skin medication for lupus and psoriasis.

The company said the agreement included research on "important inflammatory receptors like TL7 and TLR8 [as well as] broadening a range of proprietary oligonucleotides that can be used to turn various other inflammatory receptors on or off as required".

Noxopharm chief executive officer Dr Gisela Mautner said "in conjunction with the Hudson Institute team, we are making significant progress with our Sofra platform and advancing towards our goal of establishing Noxopharm as a leader in Australia in the RNA space".

Noxopharm fell 0.2 cents or 3.3 percent to 5.8 cents.

MGC PHARMACEUTICALS

MGC says an extraordinary general meeting will vote to change its name to 'Argent Biopharma', issue director options and ratify the prior issue of shares.

Last year, MGC said 96.6 percent of an extraordinary general meeting voted in favor of a 1,000-to-one consolidation (BD: Oct 26, 2023).

Today, the company said the meeting would vote to change its name to Argent Biopharma, which "more accurately reflects the future operations of the company" and if passed, it would trade on the ASX under the code 'RGT'.

MGC said the remaining 12 resolutions included the ratification of the prior issue of creditor shares and placement shares, and the issue of 120,000 options to directors Layton Mills and Daniel Robinson, each.

The meeting will be held at Suite 1, 295 Rokeby Road, Perth on March 16, 2024 at 3pm (AWST).

MGC was up 3.5 cents or 9.7 percent to 39.5 cents.

CURVEBEAM AI

Curvebeam says it will release 13,213,855 shares from ASX escrow on February 21, and February 23, 2024.

According to its most recent Appendix 2A, on February 7, 2024 there were 205,365,534 shares on issue, meaning that following the release of the shares from ASX escrow shares it would have a total of 218,579,389 shares available for trading, with a further 101,559,103 shares remaining in ASX escrow.

Curvebeam was unchanged at 23 cents.

RHINOMED

W. Whitney George says he has increased their substantial shareholding in Rhinomed from 118,257,120 shares (41.39%) to 123,579,517 shares (43.59%).

The Darien, Connecticut-based Mr George said that with Meredith George he bought 5,322,397 shares between May 17, 2023 and February 9, 2024 for $US140,045 ($A214,529), or 2.6 US cents (4.0 Australian cents) a share.

Rhinomed was up 0.2 cents or 4.9 percent to 4.3 cents with 1.6 million shares traded.

VITURA HEALTH

Vitura says it has appointed Robert Iervasi as independent chair and non-executive director, replacing interim chair Dr Marcia Walker.

Vitura said Mr Iervasi previously was Asahi Beverages chief executive officer and was currently chair at Luv-a-Duck and Charters Paper as well as a director of SPC Global.

According to his Linkedin profile, Mr Iervasi held a Bachelor of Commerce and a Bachelor of Laws from Melbourne's Monash University.

Vitura said Dr Walker had been interim chair since September 2023 and would remain as a non-executive director.

Vitura was unchanged at 24 cents.