Biotech Daily

Tuesday February 18, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: SYNTARA UP 21%;**
- MEDICAL DEVELOPMENTS DOWN 9%

*** OPTHEA COMPLETES PHASE III OPT302, AFLIBERCEPT AMD TRIAL VISITS**

*** SYNTARA: 'SNT-6302 SIGNIFICANTLY IMPROVES SCARS, IN 14 PATIENTS'**

*** ENLITIC, GE HEALTHCARE A.I. IMAGING DEAL**

*** HUNTER, NOVARTIS HEART HEALTH RESEARCH**

*** CORRECTION: QBIOTICS**

*** CARDIEX PLEADS 'SCHULTZ' TO ASX 35% PRICE QUERY**

*** CLEO: 'ONLY SOLEY FOCUSED OVARIAN CANCER BLOOD TEST COMPANY'**

*** ZELIRA RECEIVES $1.15m FEDERAL R&D TAX INCENTIVE**

*** PETER ROSSDEUTSCHER REPLACES IISA CHAIR ANDREW STEVENS**

MARKET REPORT

The Australian stock market fell 0.66 percent on Tuesday February 18, 2025, with the ASX200 down 56.1 points to 8,481.0 points. Sixteen of the Biotech Daily Top 40 companies were up, 19 fell and five traded unchanged.

Syntara was the best (see below), up 1.5 cents or 21.1 percent to 8.6 cents, with 18.6 million shares traded. Percheron improved 12.5 percent; Starpharma was up 10 percent; Curvebeam climbed 7.4 percent; SDI was up 5.75 percent; Alcidion, Aroa, Cyclopharm and Dimerix were up more than three percent; Actinogen, CSL, Emvision and Imugene rose more than two percent; Immutep and Mesoblast were up more than one percent; with EBR and Proteomics up by less than one percent.

Medical Developments led the falls, down eight cents or 9.25 percent to 78.5 cents, with 175,566 shares traded. Compumedics lost 8.1 percent; Amplia and Micro-X fell more than four percent; Avita and Polynovo were down three percent or more; Cynata, Impedimed, Opthea, Paradigm and Prescient shed two percent or more; Neuren and Resonance were down more than one percent; with 4D Medical, Clarity, Clinuvel, Cochlear, Nanosonics, Orthocell, Pro Medicus, Resmed and Telix down by less than one percent.

OPTHEA

Opthea says it has completed all 52-week patient visits in its phase III trial of OPT302, or sozinibercept, with aflibercept for wet age-related macular degeneration (AMD).

In 2021, Opthea said it had treated the first of about 1,980 patients in the US and Canada, for its two randomized, double-blind, controlled trials, evaluating the efficacy and safety of OPT-302 in combination with either ranibizumab (Shore) or aflibercept, (Coast) compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).

Last year, the company said that it had completed enrolment of all 1,984 patients in the two phase III trials (BD: May 28, 2024).

Today, Opthea said the primary endpoint in both trials was a mean change in visual acuity from baseline to week 52 for sozinibercept combination therapy compared to anti-vascular endothelial growth factor-A (VEGF-A) monotherapy.

The company said beyond week 52, patients would continue to be treated for an additional year to evaluate extended safety and tolerability up to a two-year period.

Opthea said its phase III trials were designed to support “a broad label and, if successful, enable sozinibercept to be approved for use in combination with any anti-VEGF-A therapy in wet AMD patients”.

The company said topline results from the Coast OPT-302 with aflibercept trial were expected by June 2025, with results from the Shore OPT-302 with ranibizumab trial expected in mid-2025.

Opthea chief executive officer Frederic Guerard said completing the final week-52 patient visit in the trial was “an important milestone in the development of sozinibercept, as we deliver on our mission of improving visual outcomes in patients with wet-AMD to enable fuller and healthier lives”.

Opthea fell two cents or two percent to $1.00 with 2.9 million shares traded.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says a 14-patient subset of its 42-patient, phase I trial of SNT-6302 showed “significant improvements” in scar vascularization and extra-cellular matrix remodeling.

In 2023, the then Pharmaxis said a phase I trial showed the then PXS-6302 topical cream reduced collagen in scars by 30 percent but not appearance at three months, which pointed to the need for a long study in established scars (BD: May 24, 2023).

Today, the company said additional subset data found that at three months patients receiving SNT-6302 “showed significant improvements in scar vascularization ($p = 0.03$) and extra-cellular matrix remodeling ($p = 0.03$) compared to placebo-treated patients”.

Syntara said SNT-6302 was developed as a topical treatment to modify scar composition and reduce fibrosis by inhibiting the enzyme lysyl oxidase (LOX).

The company said the 14-patient subgroup were exposed to SNT-6302 for three months, after which it used optical coherence tomography to measure changes in the deeper part of scar tissue.

Syntara said the imaging provided “compelling evidence in support of SNT-6302, with scars appearing structurally and biologically closer to normal, uninjured skin”.

The company said the subgroup data supported the previous 42-patient data.

Syntara managing-director Gary Phillips said “these new findings significantly enhance our understanding of scarring and the impact of topical pan-LOX inhibitors”.

“Combining these insights with global input from patients and clinicians, we are now in a good position to advance the development of a first-in-class treatment for scarring that addresses significant cosmetic and functional challenges,” Mr Phillips said.

Syntara was up 1.5 cents or 21.1 percent to 8.6 cents with 18.6 million shares traded.

ENLITIC

Enlitic says subsidiary Laitek will supply its artificial intelligence based medical imaging and picture archiving software to Chicago's General Electric (GE) Healthcare.

Enlitic said it used artificial intelligence (A.I.) to "develop software products that manage medical imaging data in radiology" including magnetic resonance imaging, computed tomography scans, x-ray and ultrasound images.

The company said it licenced the products to healthcare providers.

Enlitic said with its products GE Healthcare would "streamline application migrations, enabling healthcare providers worldwide to adopt advanced diagnostic and care decision capabilities more efficiently".

The company said its Ensight suite would "embed A.I. automation and data intelligence into migration tools for GE Healthcare's cloud and on-premise technology".

Enlitic said Laitek's data migration technology would "accelerate the transition of customers to GE Healthcare's newest enterprise imaging and [picture archiving and communication system]".

The company the "specific details of the collaboration" were being finalized and did not disclose the commercial terms of the agreement.

Enlitic said that GE Healthcare's artificial intelligence workflow software Centricity had been installed at 2,253 US sites, with their products serving more than one billion patients a year.

Enlitic managing-director Michael Sistenich said the deal was "more than a collaboration - it is a shift in how healthcare institutions approach data".

"We are moving beyond conventional migrations, enabling healthcare providers to move to the cloud with confidence," Mr Sistenich said.

Enlitic was up 2.6 cents or 44.1 percent to 8.5 cents with 4.9 million shares traded.

HUNTER MEDICAL RESEARCH INSTITUTE

The Hunter Medical Research Institute (HMRI) says it has a partnership with Novartis Australia to research and develop treatments for cardio-vascular health.

The Hunter Medical Research Institute said the partnership with the New South Wales' University of Newcastle would focus on "early detection of high cholesterol and lipid disorders, innovative digital tools for patient care [and] new approaches to cardio-vascular disease prevention".

The Institute said that, with Novartis, it would "develop sustainable models of care that can be expanded across Australia" and the partnership was "setting a new standard for industry-research collaboration, ensuring cutting-edge science leads to real-world impact".

HMRI said Novartis had made an investment in the partnership, but did not disclose any details about the funding.

The Institute said part of the agreement included the establishment of a steering committee, which would be responsible for identifying and prioritizing research initiatives.

HMRI said the committee would decide "which projects should be pursued, how they should be structured and what steps need to be taken to bring them to fruition".

The Institute said the committee would consist of HMRI and Novartis experts, to ensure each project was "scientifically rigorous, strategically aligned and practically achievable".

HMRI chief executive officer Prof Frances Kay-Lambkin said the partnership allowed the Institute's "affiliated researchers, University of Newcastle experts and clinicians to deliver life changing innovations at a speed unmatched in Australia, if not the world".

"Our deep connection to the community enables us to rapidly translate laboratory breakthroughs into practical healthcare solutions," Prof Kay-Lambkin said.

CORRECTION QBIOTICS

Last night's edition carried an incorrect headline saying that Qbiotics tigilanol tiglate "rapidly cleared sarcoma".
In fact, the Qbiotics poster presentation said that tigilanol tiglate was rapidly cleared from the body of sarcoma patients.
The mistake was made by the Monday sub-editor who has been rapidly cleared from Biotech Daily.
Qbiotics is a public unlisted company.

CARDIEX

Cardiex has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said that the company's share price rose 34.8 percent from a low of 11.5 cents to a high of 15.5 cents yesterday.
Cardiex fell 2.5 cents or 16.1 percent to 13 cents.

CLEO DIAGNOSTICS

Cleo says it is the "only ASX-listed company that is solely focused on the development of a diagnostic blood test for the detection of ovarian cancer".
After the market closed on Friday February 7, 2025, Cleo told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities, following a 25.7 percent increase in its share price, with the ASX noting a significant increase in the volume of shares traded (BD: Feb 10, 2025).
At that time, the company said it was "the only known medical technology company on the ASX focused on the development of its simple and accurate blood test for the early diagnosis of ovarian cancer" (sic).
Today, in a clarification to its ASX price query response, Cleo said its focus was "on addressing the urgent, unmet need for an early and accurate diagnostic for ovarian cancer, which does not exist today".
Cleo said it was progressing US clinical trials in preparation for a submission to the US Food and Drug Administration later this year.
In its Appendix 4C Quarterly Report for December 31, 2024, the company said it "continues to progress its product development strategy for its initial pre-surgical triage market".
Cleo was up 3.5 cents or 7.4 percent to 51 cents.

ZELIRA THERAPEUTICS

Zelira says it has received $1,153,000 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.
Zelira did not disclose the period when it undertook the research and development related to the incentive.
Zelira was up one cent or two percent to 51.5 cents.

INDUSTRY INNOVATION AND SCIENCE AUSTRALIA, FEDERAL GOVERNMENT

The Federal Government says Peter Rossdeutscher will replace Industry Innovation and Science Australia (IISA) chair Andrew Stevens for a three-year term.

A media release from the Federal Minister for Industry and Science Ed Husic said Industry Innovation and Science Australia was an independent statutory board that advised government on industry, innovation, science and research, monitored several government programs and promoted investment.

The Government said Mr Rossdeutscher was the chair of Quantum Australia and co-chair of First Nations X, a not-for-profit organization for Indigenous Australian innovation and start-ups, as well as having worked for more than 20 years in the quantum computing, mining, robotics and education industries.

The Federal Government said Mr Stevens had recently finished his second and final term as Industry Innovation and Science Australia (IISA) chair.

Mr Husic said Mr Rossdeutscher's "track record leading start-ups and mentoring the next generation of entrepreneurs to scale-up their firms [is] something the IISA has identified as a key priority".

"Given the need to strengthen business dynamism more broadly in our economy, having someone with Mr Rossdeutscher's experience will prove to be especially valuable," Mr Husic said.

"I also want to sincerely thank Mr Stevens for six years of leadership and service," Mr Husic said.

"He leaves IISA in a strong place and I wish him all the best in the future," Mr Husic said.