Biotech Daily

Tuesday February 6, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PERCHERON UP 12%; IMPEDIMED DOWN 10%**

*** CYCLOPHARM UNAUDITED REVENUE UP 14% TO $30m**

*** RADIOPHARM TAKES $12.5m LIND DRAW-DOWN FACILITY**

*** ALLEGRA CANCELS FDA SPINAL CAGE APPLICATION; IP FOR SALE**

*** RECCE SIGNS PT ETANA SOUTH EAST ASIA AGREEMENT**

*** ISLAND ISLA-101 SINGLE ASCENDING DOSE 'SAFETY'**

*** ALTERITY PHASE II STUDY APPROVED TO CONTINUE**

*** LTR MANUFACTURES SPONTAN FOR TRIAL**

*** CHRIS ACHURCH REPLACES NEUROSCIENTIFIC CO SEC ABBY NIVEN**

*** BIO-MELBOURNE NON-ANIMAL TESTING FORUM**

MARKET REPORT

The Australian stock market fell 0.58 percent on Tuesday February 6, 2024, with the ASX200 down 44.3 points to 7,581.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, and 10 traded unchanged.

Percheron (Antisense) was the best, up 0.7 cents or 11.7 percent to 6.7 cents, with two million shares traded. Imugene improved 9.4 percent; Dimerix and Emvision climbed more than six percent; 4D Medical was up 5.4 percent; Alcidion, Curvebeam and Prescient were up four percent or more; Medical Developments and Next Science were up more than three percent; both Cyclopharm and Orthocell rose 2.6 percent; Neuren was up one precent; with CSL and Telix up by less than one percent.

Impedimed led the falls, down 0.9 cents or 9.7 percent to 8.4 cents, with 7.1 million shares traded. Cochlear and Starpharma lost more than six percent; Actinogen and Cynata were down more than three percent; Compumedics, Genetic Signatures, Nanosonics, Opthea and Resonance shed two percent or more; Amplia, Avita, Clarity and Paradigm were down more than one percent; with Clinuvel, Polynovo, Pro Medicus and Resmed down by less than one percent.

CYCLOPHARM

Cyclopharm says unaudited revenue for the year to December 31, 2023, was up 14 percent to $28.9 million following US approval of its Technegas lung imaging device.
Last year, Cyclopharm said the US Food and Drug Administration had approved Technegas for pulmonary embolism imaging (BD: Oct 2, 2023).
Today, the company said it had more than 80 contracts covering more than 280 private and government institutions, with six contracts “executed or waiting final signatures … [and] a further three contracts nearing final draft stage”.
Cyclopharm said its US subsidiary, Cyclomedica USA LLC had been granted a Pharmaceutical Wholesale License by the Georgia Drugs and Narcotics Agency, allowing the company to import and distribute Technegas in the US.
The company said revenues included a one-off installation and training charge of $US7,000 ($A10,780), an ongoing $US7,000 a year technology fee and a 50-patient box of patient consumables valued at $US11,250.
Cyclopharm said it had appointed Dr Tina Buehner as Cyclomedica USA LLC director of medical affairs and that she had more than 25-years of experience in nuclear medicine.
The company said Dr Buehner held a Doctor of Health Sciences from Chicago’s Rush University.
Cyclopharm managing-director James McBrayer said: "We have been extremely pleased with the enthusiasm expressed by the nuclear medicine community in the US since approval”.
“We had the opportunity to witness this support at scale this past weekend at the [Society of Nuclear Medicine and Molecular Imaging,] mid-winter meeting,” Mr McBrayer said.
“This was the first meeting held since Technegas was approved [and] we were particularly pleased to see on the program a session that substantially featured the clinical and operational benefits of Technegas,” Mr McBrayer said.
Cyclopharm was up 4.5 cents or 2.6 percent to $1.76.

RADIOPHARM THERANOSTICS

Radiopharm says it has an up-to $12.5 million draw-down equity facility with New York’s Lind Partners.
Radiopharm said it would receive $1.2 million from Lind through a share subscription agreement and a further up-to $11.3 million in monthly instalments of between $50,000 to $1 million over a 12-month period in a share purchase agreement.
The company said under the agreement Lind would pay $1.2 million for shares with a deemed value of $1.44 million; and it would issue Lind 20,000,000 shares at the time of funding and a further 8,955,224 options, exercisable at nine cents each within four years, subject to shareholder approval.
Radiopharm said that the subscription price would be the lesser of 10 cents a share; and 90 percent of the average of the three lowest daily volume-weighted average prices during the prior 20 days of trading.
The company said it would pay Lind a $42,000 commitment fee representing 3.5 percent of the advance payment; and it had drawn-down a first tranche of $300,000 under the up-to $11.3 million share purchase agreement.
Radiopharm said it would pay Lind an establishment fee of $25,000 as well as 3.5 percent of the amount funded in each monthly tranche drawn-down.
Radiopharm said it could terminate the agreement at any time with a cancellation fee of $50,000, or for no fee after a minimum of $900,000 had been drawn-down.
Radiopharm was unchanged at 6.8 cents with 1.6 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says it has withdrawn its US Food and Drug Administration application for its Sr–Ht–gahnite spinal cage and hopes to sell its related intellectual property.
Last year, Allegra said the FDA had requested “more information” regarding its Sr–Ht–gahnite spinal cage application for bone healing (BD: Aug 17, Sep 28, 2023).
The company previously said Sr-Ht-gahnite was composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminum-oxide (BD: Jun 8, 2016).
Today, Allegra said it had decided to withdraw its submission following communications with the FDA and its “need for additional supporting information to support its submission”.
The company said given its “limited working capital and the additional expense now required in obtaining supporting data for [its]… submission to the FDA” it had decided “to seek a buyer for all of the intellectual property, relating to the Sr-Ht-Gahnite and Sr- Ht, including worldwide patents and all registered patents and application for patents in relation to the bio ceramic material, including the spinal fusion cage.
Allegra said the proposed sale would be subject to “the required ASX and regulatory approvals”.
In last year’s Appendix 4E and Annual Report, Allegra said that it had $1,406 in cash and cash equivalents at June 30, 2023, compared to $206,332 at June 30, 2022.
The company said that revenue was up 10.1 percent to $3,281,416 with the loss for the year up 43.9 percent to $3,647,737.
Allegra fell 0.1 cents or 3.2 percent to three cents.

RECCE PHARMACEUTICALS

Recce says it has an agreement with Jakarta’s PT Etana Biotechnologies “to accelerate the clinical development of [its] … anti-infective portfolio”.
Recce said PT Etana was research, manufacturing and marketing company for biological therapies in the Southeast Asian market and had a facility that was able to produce therapies with halal certification.
Recce chief executive officer James Graham told Biotech Daily that PT Etana would provide fill and finish services for the company’s anti-microbial products, including regulatory services for the Association of South East Asian Nations (ASEAN) countries.
Mr Graham said that PT Etana would co-ordinate the regulatory-directed trials in the region.
Recce said it would collaborate with Etana to “advance [its] … clinical program with speed, accessibility, cost-effectiveness and quality”.
The company said that by coordinating bilateral efforts between the Australia and Indonesia Governments and industry experts, the agreement would provide it “with market entry and penetration for international expansion in newly developed wealth of opportunities”.
Recce said that the agreement included “substantial Government support”.
Mr Graham said the bilateral collaboration “between Recce and Etana, signifies the Australian and Indonesian Governments’ shared commitment to advancing public health, fostering innovation, and addressing the global challenge of [anti-microbial resistance] in the Asia Pacific region”.
“By combining our expertise and resources, we can make significant strides towards a healthier and more resilient future for both our nations and the global community,” Mr Graham said.
Recce was up four cents or 8.7 percent to 50 cents.

ISLAND PHARMACEUTICALS

Island says it has completed dosing all three cohorts in its single ascending dose study of ISLA-101 for dengue fever, and that the drug was “safe and well tolerated”.
Last year, Island said it had dosed the first of 24 volunteers in its single-ascending dose study of its ISLA-101 for mosquito-borne diseases (BD: Nov 24, 2023).
Today, the company said the safety review committee confirmed each fasted dose was “safe and well-tolerated, based on a review of available preliminary data”.
Island chief executive officer Dr David Foster said the company was “delighted to receive the news that ISLA-101 has been tolerated well by our study subjects and delivered safely to them … the study's primary objective”.
Dr Foster said Island had completed all dosing and the blood samples would be analyzed for the levels of ISLA-101 in the blood.
Island fell 0.3 cents or 3.4 percent to 8.5 cents.

ALTERITY THERAPEUTICS

Alterity says it has approval to continue its 77-patient, phase II study of ATH434 in patients with multiple system atrophy.
In 2022, Alterity said it had dosed the first patients in its randomized, double-blind, placebo-controlled phase II trial; and last year, said it had enrolled all 77 patients in the trial (BD: Jul 6, 2022, Nov 8, 2023).
Today, the company said the data monitoring committee had complete its second review of the study data and “expressed no concerns about safety and recommended that the study continue without modification”.
Alterity said the plan for the committee to review initial safety data had been cleared with the US Food and Drug Administration.
Alterity chief executive officer Dr David Stamler said “with accumulated data from our phase II study, we are pleased to report that the data monitoring committee has determined that there are no safety concerns and that the study can continue as planned.”
“We remain on track to complete the study in November 2024 and report top-line data in January 2025,” Dr Stamler said.
Alterity was unchanged at half a cent with 49.0 million shares traded.

LTR PHARMA

LTR says it has completed quality control milestones in the manufacturing of its Spontan nasal spray for erectile dysfunction for its bio-equivalence clinical study.
LTR said with its contract manufacturing organization it had tested the chemical stability of Spontan in three specified periods, whilst assessing packaging integrity and confirming purity of the active ingredients.
The company said patient recruitment for its 18-volunteer, randomized, open-label, single-dose bioequivalence study of Spontan, or vardenafil, was expected to begin this month.
LTR said it had met key US Food and Drug Administration requirements to be considered a pivotal study.
LTR executive chair Lee Rodne said the achievement was “underpinned by a comprehensive suite of quality control checks as mandated by the FDA”.
“Each check was meticulously designed to evaluate the chemical stability of Spontan over specified time periods, assess the integrity of its packaging, and verify the purity of our nasal spray formulation,” Mr Rodne said.
LTR was up two cents or 6.35 percent to 33.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it appointed Chris Achurch as company secretary, effective from today, replacing chief financial officer and company secretary Abby Macnish Niven.
Neuroscientific said Chris Achurch had worked in the finance industry for more than 15 years and provided consulting services to a number of ASX listed and unlisted companies.
The company did not state whether it had begun a search for a replacement chief financial officer.
Neuroscientific chair Chris Ntoumenopoulos said Ms Niven had been “an integral part of Neuroscientific for the past four years, and we wish her every success in the future”.
Neuroscientific was unchanged at 3.7 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold a forum on advancing non-animal models in bio-medical research on February 29, 2024.
Bio-Melbourne said the forum would discuss how human-derived models such as three-dimensional-cell cultures, organoids, organ-on-chip technologies and microfluidic platforms could replace animals in research, drug discovery programs and preclinical trials and “the implications of this … for both our health-tech sector and local economy”.
The Network said speakers included Monash University’s Prof Carl Kirkpatrick, Commonwealth Scientific and Industrial Research Organisation strategy manager Laura Thomas and Australian Ethical ethical stewardship lead Amanda Richman.
Bio-Melbourne said the event would be held online and at the Swinburne Studio, Australian Centre for the Moving Image (ACMI), Federation Square, Melbourne, on February 29, 2024, from 3.45pm to 6.45pm (AEDT).
The Network said in-person tickets were $85 for members and $175 for non-members, with online registration costing $25 for members and $45 for non-members.
For more information and registration go to: https://bit.ly/486E8cp.