Biotech Daily

Tuesday December 10, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: CURVEBEAM UP 12%; PRO MEDICUS DOWN 9%**

*** LTR RAISES $25m**

*** VISIONEERING REQUESTS ASX DELISTING**

*** SYNTARA: 'SNT-5505 REDUCES BONE CANCER SYMPTOMS'; HALT**

*** CLEO STARTS OVARIAN CANCER TEST AT SILES HEALTH**

*** IMMUTEP OPENS PHASE III EFTI LUNG CANCER TRIAL**

*** ARGENICA FINAL PHASE II ARG-007 STROKE SAFETY REVIEW**

*** OPYL, L39 CAPITAL OPEN '$100m A.I. BIOTECH FUND'**

*** ANTERIS: ATGC US IPO, NASDAQ LISTING**

*** RENERVE: UNION MEDISCIENCE GULF NERVALIGN DISTRIBUTOR**

*** RADIOPHARM: 'RAD-402 SAFE, POSITIVE DATA, IN MICE'**

*** JASON CARROLL INCREASES, DILUTED TO 14.2% OF ISLAND**

MARKET REPORT

The Australian stock market fell 0.36 percent on Tuesday December 10, 2024, with the ASX200 down 30.0 points to 8,393.0 points. Sixteen of the Biotech Daily Top 40 companies were up, 15 fell, seven traded unchanged and two were untraded.

Curvebeam was the best, up 1.5 cents or 12.0 percent to 14 cents, with 172,880 shares traded. Atomo climbed 5.3 percent; Starpharma improved 4.35 percent; Emvision was up 3.7 percent; Clinuvel and Mesoblast rose more than two percent; Avita, Dimerix, Genetic Signatures, Immutep, Medical Developments, Micro-X, Neuren, Orthocell, Proteomics and SDI were up more than one percent; with CSL and Resmed up by less than one percent.

Pro Medicus led the falls on no news, down $24.04 or 9.0 percent to $244.33, with 484,393 shares traded. Resonance lost 7.35 percent; Aroa was down 5.7 percent; 4D Medical, Cyclopharm, Nanosonics and Universal Biosensors fell four percent or more; Nova Eye, Paradigm and Polynovo were down more than three percent; Clarity, Cochlear, Cynata and EBR shed two percent or more; with Alcidion, Opthea and Telix down by more than one percent.

LTR PHARMA

LTR says it has “binding commitments” to raise $25 million at 92 cents a share to accelerate the commercialization and growth of Spontan”.
LTR said the issue price was a 12.4 percent discount to the last closing price.
The company said it would use $10.5 million to fund US commercial preparations for its Spontan nasal spray formulation of vardenafil, marketed by Bayer as Levitra.
The company said $2.0 million was for regulatory activities and animal toxicity studies, $1.0 million for Spontan variations development, $4.0 million for marketing studies and website development and $6.0 million on working capital, with the remaining funds for investor relations.
LTR said Bell Potter Securities and Alpine Capital were joint lead managers to the placement.
LTR chair Lee Rodne said the funding was “a critical milestone for LTR Pharma as we advance towards commercializing Spontan in the US, Australia and other key markets”.
“With our preparations for regulatory engagement underway, and with our strategic partnerships, including our co-development agreement with Aptar Pharma, we are well-positioned to bring a first-in-class, rapid-onset treatment to market," Mr Rodne said.
LTR fell seven cents or 6.7 percent to 98 cents with 1.45 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has submitted a formal request to the ASX to be removed from the official list due to its “low trading price”, pending stockholder approval.
In 2017, Visioneering said it raised $33.3 million in an underwritten initial public offering at 42 cents per Chess depository instrument (CDI) to list on the ASX and commercialize its Naturalvue contact lenses (BD: Mar 16, 2017).
At that time, the Alpharetta, Georgia-based company said that the Naturalvue multi-focal, one-day contact lenses had US Food and Drug Administration approval and were used for presbyopia and paediatric myopia.
Today, Visioneering said its board considered the delisting to “be in the best interest of the company and its securityholders for a number of reasons, including the low trading price of the company’s CDIs [and] relatively low levels of trading liquidity”.
The company said that the “value attributed to a CDI has been largely independent of news flows, even when positive news has been released” and that a delisting would “allow a more objective and independent appraisal of valuation to take place”.
Visioneering said raising capital as an unlisted entity would allow it to undertake larger, less dilutive capital raisings and the costs of raising capital on the ASX were higher than the expected costs of raising capital if it were to delist.
The company said it had “evaluated strategic opportunities and corporate transactions, including a potential sale of the company” and that it understands its largest securityholder, Alex Waislitz’s Thorney, would “be unwilling to sell its holding in the company based on a valuation reflective of the company’s present market capitalization, even if a meaningful premium was offered to the current trading price”.
Visioneering said further reasons for the delisting included the administrative, compliance and direct costs of its ASX listing, management’s time and becoming a more attractive employer and promoting employee retention.
The company said stockholders would vote to approve the delisting at a special meeting “to be held on or around January 10” with delisting on February 10, 2025.
Visioneering fell as much as 61.5 percent to 5.2 cents before closing down 7.8 cents or 57.8 percent at 5.7 cents, with 833,827 shares traded.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says six of 13 evaluable myelofibrosis patients in its phase II trial of SNT-5505 with ruxolitinib had a 50 percent improvement of symptoms from baseline.

Earlier this year, Syntara said it dosed all 15 patients in the phase II trial of SNT-5505 with ruxolitinib for bone marrow cancer myelofibrosis (BD: Jul 31, 2024).

Today, the company said that at 12 weeks of treatment six (46.15%) of 13 evaluable patients "achieved a 50 percent improvement in total symptom score".

Syntara said improvement in total symptom score was 80 percent in four of five evaluable patients at 38 weeks of treatment.

The company said nine (81.8%) of 11 evaluable patients, achieved stable or reduced spleen volume with no dosage adjustments in ruxolitinib.

Syntara said three (33.3%) of the 10 evaluable patients, at week 38, achieved a spleen volume reduction of 25 percent and two patients had a reduction of 35 percent, both considered "clinically meaningful".

The company said patients enrolled had a median ruxolitinib "exposure of 3.2 years and a median baseline symptom score of 23, indicative of a high disease burden".

Syntara said haemoglobin levels and platelet counts were "generally stable across the cohort, with few major haematological toxicities reported".

The company said one of two transfusion dependent patients showed reduced transfusion requirements, about 70 percent reduction from baseline, for the period of the interim data.

Syntara said patient symptoms and spleen volume continued to improve for the duration of the interim data which was "a novel finding that differentiates SNT-5505 from [myelofibrosis] drugs on-market and in later stages of development".

The company said SNT-5505 was safe and well-tolerated, with no treatment related serious adverse events noted at the interim stage.

Syntara said 12 of the 16 enrolled patients were continuing to receive treatment as of the interim data cut off, and since then a further three patients had discontinued after receiving six months of therapy.

The company said no discontinuations for adverse events were considered related to SNT-5505 treatment and that the level of discontinuation in clinical trials was "consistent with a patient group with a high disease burden".

Syntara said once it received data from a subset of patients reaching 52 weeks of treatment by March 2025, it intended "to discuss with the FDA the trial design for a pivotal phase IIc/III study" and would engage with potential partners.

Syntara managing-director Gary Phillips said a well-tolerated drug that produced "increasing and durable benefit the longer patients stay on is an exciting prospect and would differentiate SNT-5505 from other [myelofibrosis] drugs on the market and in development".

"The changes in symptom score seen in the interim data at nine months, albeit from a relatively small cohort of patients, suggests a superiority to other drugs that have been trialed in this patient group and are particularly important given the emphasis that the FDA and other regulatory bodies place on this measure," Mr Phillips said.

Syntara said that further data would be released by the end of the year and final data by July 2025.

Separately, Syntara requested a trading halt "pending an announcement … to the market in relation to the outcome of a capital raising by way of a placement".

Trading will resume on December 12, 2024, or on an earlier announcement.

Syntara last traded at 6.7 cents.

CLEO DIAGNOSTICS

Cleo says it will open its ovarian cancer blood test trial at the Melbourne-based Siles Health's 13 Victorian clinics.
Earlier this year, Cleo said it had recruited the first of "a minimum of 500 patients" in a US trial of its ovarian cancer blood test (BD: Sep 6, 2024).
Later, the company said Melbourne's Royal Women's Hospital would join the trial of its blood test for the early detection of ovarian cancer (BD: Nov 27, 2024).
Today, Cleo said conducting the trial at Siles Health would provide "important insights into clinical workflows that will ultimately support clinical implementation strategies for successful market adoption [the] … ovarian cancer blood test".
The company said the agreement would allow it to access "a larger cohort of patient samples that may bolster the [US Food and Drug Administration]-enabling US trial … [and] continue to expand broader market awareness for Cleo" as well as verifying the test.
Cleo executive director Dr Richard Allman said as the company progressed "through our clinical trials initiatives, our focus continues on how this ultimately supports successful market adoption of Cleo's ovarian cancer blood test, specifically in the US, as our first market in the next year".
"In this context, the partners that Cleo is engaging play an important role in how the company is executing on its ambition to transform ovarian cancer diagnostics."
Cleo was up two cents or 5.8 percent to 36.5 cents.

IMMUTEP

Immutep says it has opened its 750-patient, phase III trial of eftilagimod alpha, or 'efti', with chemotherapy for metastatic, non-small cell lung cancer, in Australia.
In June, Immutep said it would conduct a 750-patient, randomized, double-blind, controlled phase III trial of efti for lung cancer (BD: Jun 3, 2024).
At that time, the company said the trial would evaluate the combination of efti with Keytruda and standard-of-care chemotherapy compared to Keytruda and standard-of-care chemotherapy alone, or placebo.
Later, Immutep said it had "positive feedback" from the US Food and Drug Administration for its phase III trial of efti for lung cancer (BD: Jul 22, 2024).
Today, the company said it had completed regulatory submissions "to the vast majority of the more than 25 countries that will be part of the … trial" and expected the first Australian patient to be enrolled by April 2025.
Immutep said the trial had dual primary endpoints of progression-free survival and overall survival and would include more than 150 clinical sites.
The company said Australia was the first approval, with UK approval expected "shortly" and approvals from multiple countries "expected in the weeks and months ahead".
Immutep managing-director Marc Voigt said Australian Therapeutic Goods Administration approval to commence the trial was "a significant milestone for Immutep and marks its transformation into a phase III company".
"This also represents a key step towards potentially establishing a new standard-of-care for patients with metastatic [non-small cell lung cancer]," Mr Voigt said.
"We are confident based on the strength of eftilagimod alfa's data that it can make a meaningful difference in cancer patients' lives, and we eagerly anticipate enrolling the first patient into this important study during the first quarter of 2025," Mr Voigt said.
Immutep was up half a cent or 1.5 percent to 34 cents with 3.7 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it will conduct a final safety review following the dosing of 74 patients in its 92-patient, phase II trial of ARG-007 for stroke “at the end of January”.
Earlier this year, Argenica said it had dosed the first cohort in the study of ARG-007 for acute ischaemic stroke, with no adverse events reported (BD: Apr 10, 2024).
Later, the company said it had opened eight of 10 trials sites and that three data safety board reviews of the first five, 18 and 46 patients recommended the study continue “with no modifications” (BD: Apr 29, Jul 24, Sep 6, Nov 1, 2024).
Today, Argenica said having reached the 75 percent recruitment milestone the independent data safety monitoring board would “conduct one more meeting at the end of January 2025 to assess patient data from patients 47 to 69 and make a recommendation as to whether the study may continue as per the study protocol”.
The company said enrolment would not be halted during the planned safety review.
Argenica said it was currently preparing an investigational new drug application for the US Food and Drug Administration as it was necessary for “any future later phase clinical trials of ARG-007 to be undertaken at sites in the US”.
The company said it was “on track to complete dosing of all patients before the recruitment target of the end of [the three months to June 30, 2025]”.
Argenica managing-director Dr Liz Dallimore said that the pace of recruitment in the trial had “exceeded our expectations and we are grateful for the dedication and hard work of the teams at the trial sites … [and the company was] working tirelessly to set Argenica up for later stage clinical trials to test the efficacy of ARG-007 in stroke”.
Argenica was up 1.5 cents or 2.3 percent to 67 cents.

OPYL

Opyl says with L39 Capital Pty Ltd it has opened the ‘A.I. Biotech Fund’ to invest $100 million in biotechnology companies using its Trialkey clinical trials analysis software.
Opyl said it was “targeting funds under management of $100 million over three years” and would receive a $25,000 software licence fee as well as 25 percent of the fund’s income.
The company said the fund’s strategy was “built around Trialkey’s real-time predictive analytics, identifying moments of peak value creation during clinical trials”.
Opyl said Trialkey had “92 percent accuracy in predicting clinical trial completion” and would “support up-to 200 precision trades annually, with an initial focus on 20 investments in the US and Australia”.
The company said the “data-backed methodology aims to reduce risk and improve returns, providing investors with unparalleled access to high-potential biotechnology and pharmaceutical companies”.
Opyl said the “average clinical trial has a 28 percent chance of success yet Trialkey has uncovered trials with over 82 percent chance of success”.
The company said with Melbourne’s L39 Capital the fund was supported by investments from director Antanas ‘Tony’ Guoga and executive director Damon Rasheed.
Last month, Opyl said its annual general meeting passed all resolutions by more than 99.46 percent, but that it withdrew the special resolution to change the company name to ‘Trialkey Limited’ (BD: Nov 29, 2024).
The company said the fund was open for applications to wholesale and sophisticated investors, with a minimum investment of $50,000.
Email info@aibiotechfund.com or go to: www.aibiotechfund.com for the interest form.
Opyl was up 0.3 cents or 10.3 percent to 3.2 cents, implying a market capitalization of $5.5 million.

ANTERIS TECHNOLOGIES

Anteris says its US-based holding company Anteris Technologies Global Corp (ATGC) has opened an initial public offer of 14,800,000 shares to list on the Nasdaq.
Last month, Anteris said its scheme meeting voted to redomicile to the US and Nasdaq listing through the Delaware-based ATGC, and last week, said it had court approval for the schemes, with final ASX trading on December 5 (BD: Nov 13, Dec 3, 5, 2024).
Today, the company said ATGC intended to grant the underwriters a 30-day option to purchase up-to an additional 2,220,000 shares of common stock from ATGC "at the initial public offering price, less underwriting discounts and commissions".
Anteris did not disclose the issue price of shares in the initial public offer.
The company said ATGC had applied to list the shares on the Nasdaq under the ticker code 'AVR', and intended to list Chess depository interests (CDIs) on the ASX under the code AVR following the US initial public offer, with each CDI to be equal to one US share.
Anteris said the funds would be used for the development of its Duravr transcatheter heart valve and the preparation and enrolment of a randomized, pivotal study in severe aortic stenosis, with the remainer for working capital and repaying its convertible note facility.
The company said TD Cowen, Barclays Capital and Cantor Fitzgerald were acting as joint book-running managers to the offer, with Lake Street Capital Markets lead manager.
Anteris has been removed from the official list and last traded at $10.54.

RENERVE

Renerve says Manama, Bahrain's Union Mediscience BSC will exclusively distribute its Nervalign nerve cuff for peripheral nerve repair in five Persian Gulf states.
Last month, Renerve raised $7 million in initial public offer at 20 cents a share to commercialize its nerve repair products including Nervalign (BD: Nov 26, 2024).
Today, the company said the agreement included rights in Bahrain, Saudi Arabia, Kuwait, the United Arab Emirates and Qatar, but did not disclose the commercial terms.
Renerve said it was accelerating its expansion in the Middle East.
Last week, Renerve said Accession Medical Supplies Co would market and sell Nervalign in Hong Kong and Macau (BD: Dec 3, 2024).
Renerve fell one cent or 5.9 percent to 16 cents with 1.1 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says studies show RAD-402 for pancreatic cancer has reported "no observed adverse effects … [and] high tumor targeting", in mice.
Radiopharm said the pre-clinical proof-of-concept dataset for its Kallikrein-related peptidase 3 (KLK3)-targeting radio-therapeutic, RAD-402 provided "a strong rationale for first-in-human clinical studies".
The company said KLK3 was expressed in the prostate, and most adeno-carcinomas of the prostate, including their metastases and that the prostate cancer biomarker prostate specific antigen was encoded by the KLK3 gene.
Radiopharm said RAD-402 was an anti-KLK3 monoclonal antibody, labelled with the radionuclide terbium-161, which compared to Lutetium-177, for "potentially improved anti-tumoral therapeutic efficacy".
The company said manufacturing of RAD-402 and the conjugate were currently ongoing and were expected to be completed by April 2025.
Radiopharm said it was on-track to begin a first-in-human, phase I study by 2026.
Radiopharm fell 0.8 cents or 19.5 percent to 3.3 cents with 50.5 million shares traded.

ISLAND PHARMACEUTICALS

Jason Carroll says he has increased his substantial shareholding in Island and been diluted from 25,025,920 shares (16.24%) to 25,591,981 shares (14.16%).

The Melbourne-based Mr Carroll said that between October 14 and November 27, 2024 he sold 410,680 shares for $79,315, or 19.3 cents a share and bought 976,741 shares in a capital raising on December 5, 2024 for $68,372, or 7.0 cents a share.

Earlier this year, Island said it had “firm commitments” to raise $3.5 million in an institutional placement at seven cents a share (BD: Oct 3, 2024).

Island was unchanged at 15 cents.