Biotech Daily

Thursday December 8, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 6%; PRESCIENT DOWN 7%**

*** IMAGION MAGSENSE 'HELPS DISCRIMINATE CANCEROUS NODES'**

*** ACTINOGEN TREATS 1st XANAMEM DEPRESSION TRIAL PATIENT**

*** STARPHARMA STARTS UK VIRALEZE POST-MARKET COVID-19 STUDY**

*** ARGENICA BEGINS FINAL PHASE I ARG-007 COHORT**

*** IMMUTEP: WUXI PRODUCES 2,000L IMP321 (EFTI)**

*** OSTEOPORE INDONESIA, MALAYSIA DISTRIBUTION**

*** MICROBA APPOINTS SYNLAB ITALY, PORTUGAL DISTRIBUTOR**

*** BOTANIX: US FDA CONFIRMS SOFPIRONIUM BROMIDE SWEAT REVIEW**

*** CARDIEX TAKES 'MATERIAL CONTRACT' HALT TO SUSPENSION**

*** REGAL TAKES 7.9% OF PHARMAXIS**

*** AUDEARA APPOINTS STUART SMITH CFO**

*** 4D MEDICAL APPOINTS MATT TUCKER FOR BUSINESS DEVELOPMENT**

MARKET REPORT

The Australian stock market fell 0.75 percent on Thursday December 8, 2022, with the ASX200 down 53.9 points to 7,175.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and one was untraded.

Dimerix was the best, up one cent or 6.45 percent to 16.5 cents, with 73,100 shares traded. Next Science improved 4.5 percent; Nova Eye climbed 3.45 percent; Imugene and Universal Biosensors rose more than two percent; Clinuvel, Immutep, Pharmaxis, Polynovo, Proteomics and Volpara were up more than one percent; with Paradigm, Pro Medicus and Resmed up by less than one percent.

Prescient led the falls, down one cent or 6.7 percent to 14 cents, with one million shares traded. Alcidion, Atomo, Emvision, Genetic Signatures, Kazia and Orthocell fell three percent or more; Antisense; Compumedics, Mesoblast, Neuren and Uscom shed two percent or more; Cochlear, Cyclopharm, Cynata, Medical Developments and Impedimed were down one percent or more; with CSL, Nanosonics, Opthea and Telix down by less than one percent.

IMAGION BIOSYSTEMS

Imagion says its Magsense HER-2 breast cancer imaging agent can “help discriminate potentially cancerous nodes from normal nodes”.
In March, Imagion said an evaluation of the first five patients in its first-in-human study showed that its Magsense breast cancer imaging agent was safe and well tolerated (BD: Mar 17, 2022).
Last year, the company said it had enrolled the first of about 15 patients in the phase I trial of the Magsense imaging agent as an aid in the staging of human epidermal growth factor receptor-2 positive (HER2+) breast cancer by detecting if the tumor had spread to the lymph nodes (BD: May 26, 2021).
Today, Imagion said it presented the interim data from the trial in a poster at the San Antonio Breast Cancer Symposium in Texas, from December 6 to 10, 2022, which was available at: https://info.imagionbio.com/sabcs-2022-breast-cancer-poster-request.
Imagion said that when Magsense was combined with standard morphological assessments, the imaging agent had “the potential to improve radiological evaluation thereby improving the standard-of-care clinical assessments”.
The company said that changes in magnetic resonance contrast created by the specific binding of the Magsense imaging agent to tumor cells in the nodes aided in resolving nodal status, and that the imaging agent was detectable by magnetic relaxometry.
Imagion said that “more subject samples are needed due to the limited amount of accessible dissected nodal tissue to-date”.
Imagion chief executive officer Bob Proulx said the results “focused on the study protocol’s first cohort of six patients only, and though the number of patients might seem small, the implications for the company are large as they provide the first proof-of-principle of our targeted nanoparticle technology in the clinical setting”.
“Evidence in real patients that our nanoparticle technology could improve upon conventional medical imaging methods is a major milestone,” Mr Proulx said.
Imagion was up 0.7 cents or 28 percent to 3.2 cents with 40.2 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it has treated the first of 160-patients in its, randomized, controlled, phase II trial of the effects of Xanamem on patients with major depression disorder.
In June, Actinogen said it was planning a six-week, phase II, major depressive disorder proof-of-concept, placebo-controlled study of 10mg Xanamem daily or placebo, in addition to anti-depressant therapy, to test the effects on both depression and cognition, with results expected in late 2023 or 2024 (BD: Jun 14, 2022).
Today, the company said the ‘Xanacidd’ trial would enrol about 160 patients, rather with results expected by “late 2023, or early 2024”.
Actinogen said the trial would include patients with persistent major depressive disorder and cognitive difficulties, despite a standard course of anti-depressant therapy.
Actinogen managing-director Dr Steven Gourlay said the company was “very pleased to announce the formal start of our trial in patients with major depressive disorder and cognitive impairment who are inadequately treated by their current anti-depressant medication”.
“There is a strong scientific rationale for reducing brain cortisol levels to improve symptoms in depression,” Dr Gourlay said. “Xanamem has the potential to be an effective low-dose daily oral therapy for the treatment of depression, Alzheimer’s disease and many other neurological conditions … alone or in combination with other treatments”.
Actinogen was unchanged at 11.5 cents with 1.9 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it has begun a 160-patient, randomized, double-blinded, post-market UK study to assess the anti-viral performance of its Viraleze nasal spray on Covid-19.
Starpharma said the study at St Peter's Hospital in Surrey would assess the severe-acute-respiratory-syndrome coronavirus-2 (Sars-Cov-2) viral load in the nasal cavity of recently diagnosed Covid-19 patients using either Viraleze or a placebo nasal spray, with the primary endpoint of viral load over a seven-day treatment period.
Previously, the company said that Viraleze protected against the Sars-Cov-2 Omicron strain, in mice, and that Viraleze reduced the viral load of Sars-Cov-2 by more than 99.9 percent in-vitro and in mice (BD: Jul 27, Aug 23, 2021; Jul 20, 2022).
Today, Starpharma said the study would examine the ability of Viraleze to prevent disease progression and worsening of symptoms and shorten the duration of symptoms in patients with Covid-19, as well as build on the existing safety and tolerability data.
Starpharma said participants would receive either Viraleze or a placebo nasal spray, four times daily, for seven days, with swabs collected to assess viral load in the nasal cavity.
The company said that the post-market study would generate "valuable clinical data on the antiviral performance of Viraleze in a controlled setting in non-hospitalised participants with Covid-19".
"The resulting data will support ongoing marketing and commercial activities and will build on the extensive in-market experience with the product," the company said.
Starpharma said the study would generate additional safety and efficacy data, relevant to new European medical device regulations on products of this category from mid-2024.
The company said Viraleze contained SPL7013, the active ingredient in Vivagel BV for bacterial vaginosis and its Vivagel condom coatings.
Starpharma was unchanged at 52.5 cents.

ARGENICA THERAPEUTICS

Argenica says it has safety review approval to begin the fourth and final cohort of dosing in its 32-subject, phase I trial of ARG-007.
In November, Argenica said it has dosed the third cohort, with no serious safety issues 24 hours after dosing (BD: Nov 25, 2022).
Today, the company said that of the eight participants in the third cohort, there were "no clinically relevant abnormal results due to administration of ARG-007" and the trial could progress to the next dose escalated cohort, with a final trial update in "late December".
Argenica fell 1.5 cents or three percent to 48 cents.

IMMUTEP

Immutep says China's Wuxi Biologics has produced 2,000 litres of eftilagimod alpha, or efti or IMP321, for late-stage clinical trials and commercial products.
The company said the Jiangsu-based Wuxi Biologics successfully performed the first 2,000 litre manufacturing run and met all predefined release criteria.
Immutep chief executive officer Marc Voigt said the company was "pleased to announce this significant achievement reaching commercial scale in efti's manufacturing by Wuxi Biologics, an important long-term partner".
Mr Voigt said that with potential registration trials in multiple indications, including our ongoing randomized Tacti-003 phase IIb trial in first line head and neck cancer, manufacturing run was "an important step towards potential commercial production of efti".
Immutep was up half a cent or 1.4 percent to 35.5 cents.

OSTEOPORE

Osteopore says it will sell its dental mesh and plug implants in Indonesia and has a distribution agreement with Avero to sell its oral and maxillofacial products in Malaysia.
Osteopore said the Indonesian Ministry of Health had approved the sale of its Osteomesh dental mesh and Osteoplug dental plug.
The company said Indonesia was “a large potential commercial opportunity for the company’s implants, which have applications for guided bone regeneration, immediate implant loading, and socket preservation”.
Osteopore said it had a two-year, exclusive distribution agreement with the Puchong, Malaysia-based Avero Mednav Sdn Bhd to promote and sell its oral and maxillofacial products, which were approved for sale in Malaysia.
Osteopore said that the agreement did not contain binding minimum sales thresholds, and there was no guarantee that the agreement would result in a material amount in sales.
Osteopore was unchanged at 20 cents.

MICROBA LIFE SCIENCES

Microba says it has agreements with Synlab International GmbH subsidiaries to distribute its gut microbiome testing technologies in Italy and Portugal.
Microba said that in 2020, it had entered a “master agreement” with the Munich, Germany-based Synlab to deliver its testing to healthcare providers in Spain, and in 2022, expanded the agreement to include additional countries in Europe and Latin America.
The company said it had an agreement with Synlab Italia Srl for two years of exclusive distribution rights for healthcare providers and then non-exclusive rights to December 31, 2028 in Italy.
Microba said it had an agreement with Synlabhealth II SA for non-exclusive rights for healthcare providers until December 31, 2028, in Portugal.
Microba head of services Berne Woodcroft said he was “pleased by our recent progress in distribution expansion with Synlab, Europe’s largest medical diagnostics company”.
“Italy represents a major market for gut health and the microbiome, and we are excited to get our testing into the hands of clinicians and patients across these two regions,” Mr Woodcroft said.
Microba was up 1.5 cents or 4.8 percent to 32.5 cents with one million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has confirmed that its sofpironium bromide new drug application for sweating was “formally under review”.
In September, Botanix said it had filed its new drug application for sofpironium bromide topical gel with “very high statistical significance” for primary axillary hyperhidrosis, the medical condition which caused excessive underarm sweating (BD: Sep 26, 2022).
Today, the company said the FDA did not identify any filing issues or require an advisory committee meeting, with the review “on track” for approval by October 2023.
Botanix chair Vince Ippolito said the company was “very pleased that the [new drug application] for sofpironium bromide has been accepted for substantive review by FDA”.
Mr Ippolito said the company looked forward to an expected mid-cycle review by April 2023 which would provide the FDA “an opportunity to discuss the review status, key findings, timelines and any other issues relating to the NDA review which will be communicated to Botanix and allow us to align our commercialization plans accordingly”.
Botanix was unchanged at six cents with 1.1 million shares traded.

CARDIEX

Cardiex has requested a suspension to follow its trading halt for an announcement “of a material contract in relation to its clinical trial revenue” (BD: Dec 8, 2022).
Trading will resume on December 9, 2022 or on an earlier announcement.
Cardiex last traded at 31 cents.

PHARMAXIS

Regal Funds Management says it has again become substantial in Pharmaxis with 56,749,640 shares or 7.89 percent.
Last week, Regal said that it had reduced its holding in Pharmaxis to below the five percent substantial threshold, selling shares from October 27 to November 30, 2022, with the single largest sale on October 28 of 806,392 shares for $50,641 or 6.3 cents a share (BD: Dec 5, 2022).
After the market closed last night, the Sydney-based Regal said it bought 38,439,773 shares on October 10, 2022 for $2,306,386 or six cents a share, and on December 5, 2022 it bought 25,726,894 shares for 1,543,614 or six cents a share.
In October, Pharmaxis said it had raised $10 million in a two-tranche placement at six cents a share (BD: Oct 19, 2022).
Pharmaxis was up 0.1 cents or 1.6 percent to 6.3 cents.

AUDEARA

Audeara says it has appointed Stuart Smith as its chief financial officer, effective immediately.
Audeara said Mr Smith had previously worked for PWR Holdings as chief financial officer and at Pacific Star, AAPT Cellular One and Redflow.
According to his Linkedin page, Mr Smith held a Bachelor of Commerce from the University of Kwazulu-Natal in Durban, South Africa.
In October. Audeara said that chief financial officer and company secretary Malcolm Thompson had resigned “due to personal circumstances” (BD: Oct 6, 2022).
The company said at that time that Stephen Buckley had been appointed as company secretary on September 21, 2022.
Audeara was up 0.15 cents or 1.8 percent to 8.65 cents.

4D MEDICAL

4D Medical says it has appointed Matt Tucker as head of business development and strategy, effective from today.
4D Medical said Mr Tucker had “extensive medical imaging knowledge” previously working for GE Healthcare Australia and New Zealand as its chief executive officer, and previously Sonosite and Phillips.
According to his Linkedin page, Mr Tucker held a Bachelor of Science from the University of South Australia.
4D Medical was up one cent or 2.4 percent to 42 cents.