Biotech Daily

Wednesday January 24, 2024

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: PROTEOMICS UP 6%**
- NANOSONICS DOWN 33%

*** US FDA WARNS OF CAR-T THERAPY HOSPITALIZATION, DEATHS**

*** NANOSONICS H1 REVENUE DOWN 2.5% TO $80m**

*** MACH7 H1 REVENUE DOWN 19% TO $13m; RECURRING REVENUE UP 9%**

*** GENETIC SIGNATURES RIGHTS RAISE $8m; TOTAL $15.9m**

*** RADIOPHARM PLACES $1.7m OF $7.9m SHORTFALL; TOTAL $3.8m**

*** AUSCANN LENDS EUROCANN FURTHER $1.7m**

*** BIOXYNE JUMPS 33% TO 1.6c ON $10m POTENTIAL MARIJUANA ORDERS**

*** CONTROL BIONICS US $577k FOR DROVE WHEELCHAIR MODULE**

*** ACTINOGEN: 'XANAMEM PENETRATES BRAIN, SAFE'**

*** KARST PEAK SELLS 79.5m SYNTARA SHAREHOLDING**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Wednesday January 24, 2024, with the ASX200 up 4.3 points to 7,519.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and one was unchanged. All three Big Caps fell.

Proteomics was the best, up five cents or 6.25 percent to 85 cents, with 187,893 shares traded. Prescient climbed 5.3 percent; Atomo and Universal Biosensors were up more than four percent; Impedimed improved 3.85 percent; Genetic Signatures and Paradigm rose more than two percent; 4D Medical, Avita and Emvision were up one percent or more; with Neuren and Volpara up by less than one percent.

Nanosonics led the falls, down $1.46 or 33.4 percent to $2.91, with 10.8 million shares traded. Dimerix lost 7.7 percent; Alcidion was down 6.45 percent; Medical Developments and Syntara (Pharmaxis) fell five percent or more; Clarity was down 4.7 percent; Nova Eye and Percheron (Antisense) were down more than three percent; Amplia, Immutep, Next Science and SDI shed two percent or more; Cochlear, Opthea, Orthocell and Telix were down one percent or more; with Clinuvel, CSL, Pro Medicus and Resmed down by less than one percent.

US FOOD AND DRUG ADMINISTRATION

The US Food and Drug Administration says it has warned manufacturers of autologous chimeric antigen receptor T-cell (CAR-T-cell) immunotherapies of risks, including deaths.
In its January 23, 2024 'FDA Roundup' the FDA said that on January 19, it "issued safety labeling change notification letters to all manufacturers of licensed BCMA-directed and CD19-directed genetically modified autologous CAR T-cell immunotherapies requiring a revision to the package insert due to risk of T-cell malignancies, with serious outcomes, including hospitalization and death".
Biotech Daily counted 12 Australian companies and organizations which previously said they were developing CAR-T-cell therapies.
In 2022, the Walter and Eliza Hall Institute said it had developed a way to potentially reduce the toxic side-effects of Car-T-cell immunotherapy treatments (BD: Jun 21, 2022).
In 2018, Cynata said it had filed an Australian patent application to cover its Cymerus technology for Car-T therapy side effects (BD: Apr 20, 2018).
In its January 23, 2024 'FDA Roundup' the FDA said it "considers the serious risk of T-cell malignancy to be applicable to all BCMA and CD19-directed genetically modified autologous T cell immunotherapies".
"The letters notify manufacturers of each such licenced product to update the package insert to include available information related to the risks and to update the Medication Guide for these products to identify the possibility of the increased risk of getting cancers, including certain types of cancers of the immune system," the US regulator said.
The FDA said that in November 2023 it "posted a safety communication to provide information related to the receipt of reports of T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA or CD19-directed autologous CAR T cell immunotherapies".
"Reports were received from clinical trials and/or post-marketing adverse event data sources," the Administration said.
"Although the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA continues to investigate the identified risk of T-cell malignancy with serious outcomes, including hospitalization and death," the FDA said.
"Patients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies," the FDA said.
"In the event that a new malignancy occurs following treatment with these products, clinicians are encouraged to contact the manufacturer to report the event and obtain instructions on collection of patient samples for testing for the presence of the chimeric antigen receptor transgene," the FDA said.

NANOSONICS

Nanosonics says unaudited revenue for the six months to December 31, 2023 was down 2.45 percent to $79.6 million, compared with the prior corresponding period.
Nanosonics said it expected revenue from Trophon ultrasound probe disinfectants and products for the six months to June 30, 2024 to improve.
The company said it expected net profit before tax for the six months to December 31, 2023 to fall 57 percent to $4.9 million, compared with the previous corresponding period.
Nanosonics said installations of Trophon products fell 13.4 percent to 1,100 units for the six months, with Trophon upgrades down 22.5 percent to 620 units during the period.
The company said it expected the total installed base to increase 3.4 percent to 33,550 Trophon units in the six months to December 31, 2023.
Nanosonics fell $1.46 or 33.4 percent to $2.91 with 10.8 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says unaudited revenue for the six months to December 31, 2023 was down 19 percent to $13.3 million, compared to the prior corresponding period.
Mach7 said the fall in revenue was due to the transition to a subscription business with annual recurring revenue up nine percent to $18.6 million for the six months to December 31, 2023, compared to $17.0 million for the six months to June 30, 2023.
The company said that unaudited total contract value from sales of its Enterprise imaging product and data management software for the six months was up 92 percent to $49.5 million for the six months to December 31, 2023, compared to the previous corresponding period.
Mach7 said it expected sales orders for the year to June 30, 2024 to be about $60 million, with revenue of $27 million and $30 million.
Mach7 chief executive Mike Lampron said “the first half has been a record-breaking period for Mach7 as we achieved our [2023-’24] target for sales orders of $48 million in the first six months of the year”.
“Continued loyalty from existing customers was evident with the bulk of sales orders representing contract renewals,” Mr Lampron said.
“Many of these customers as well as new customers have opted for subscription rather than capital licences … a trend that is gaining momentum and is also reflected in the composition of our sales pipeline,” Mr Lampron said.
“Consequently, we have revised our 2023-’24 revenue guidance downward due to the changing customer preference for a subscription model and the different timeframes from a capital to subscription model means that we will have higher quality recurring revenue that will provide greater earnings reliability and less volatility,” Mr Lampron said.
Mach7 was up 0.75 cents or 1.1 percent to 71 cents.

GENETIC SIGNATURES

Genetic Signatures says its fully-underwritten rights issue at 37 cents a share raised about $6.9 million, taking the total raised with the placement to $15.9 million.
Last year, Genetic Signatures said its placement at 37 cents a share raised about $8 million, to be followed by a one-for-6.5 rights issue for $7.9 million (BD: Dec 21, 2023).
Today, the company said the $1.1 million rights issue shortfall would be allocated to joint lead managers and underwriters Bell Potter Securities and Taylor Collison.
Genetic Signatures said the funds would be used for regulatory approvals, customer installations, research and development and general working capital.
Genetic Signatures was up one cent or two percent to 50 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has “commitments” for about $1.7 million of the $7.9 million shortfall from its 7.0 cents a share rights offer, taking the total raised to $3.8 million.
Last year, Radiopharm said its one-for-2.35, non-renounceable entitlement offer at seven cents a share raised about $2.1 million of a hoped-for $10 million, leaving a shortfall of about $7.9 million (BD: Dec 8, 2023).
Today, the company said the funds would be used to support its clinical programs.
Radiopharm was unchanged at 7.5 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has loaned the European Cannabis Corporation EUR1.0 million ($A1.65 million) for marketing HAPA 2.0 medical marijuana products in Germany.
Auscann said the loan had an interest rate of 7.5 percent per annum and was repayable by March 31, 2024.
Last year, the company said it had refreshed the documentation of its European Cannabis Corporation $8,050,000 loan at an interest rate of 10 percent a year to be repaid by June 30, 2024 (BD: Oct 26, 2023).
Today, Auscann said it was “actively seeking opportunities which would add value to the company and enable … [it] to seek re-quotation of its shares on the official list of ASX”.
Auscann was in a suspension and last traded at four cents.

BIOXYNE

Bioxyne chair Tony Ho says the Canxchange joint venture has about $10 million in sales and purchase bids for marijuana products in its first month.
Last year, Bioxyne said that subsidiary Breathe Life Sciences had a joint venture with Canxchange to launch an artificial intelligence, business-to-business, online marijuana marketplace (BD: May 22, Aug 15, 2023).
In August, the company said that London’s Canxchange was a business-to-business marijuana platform in Europe that provided digital exchange venues, payment, compliance and data services, to facilitate wholesale trading between licenced buyers, sellers, cultivators and manufacturers.
Today, Mr Ho told Biotech Daily that while there was the potential for $10 million worth of exchange, there had been no confirmed sales and Bioxyne would receive a percentage of confirmed sales.
Mr Ho said that the Canxchange system became operational in late December and the offers and bids had been generated since that time.
Yesterday, Bioxyne climbed 0.4 cents or 33.3 percent to 1.6 cents on the publication of the information in a marijuana business journal.
Today, Bioxyne fell 0.2 cents or 12.5 percent to 1.4 cents.

CONTROL BIONICS

Control Bionics says it received a $US379,492 ($A576,862) from the US Amyotrophic Lateral Sclerosis (ALS) Association to develop its Drove autonomous wheelchair module.
Last year, Control Bionics said it launched “the world’s first autonomous driving wheelchair module” using its Neuronode thought-to-computer technology (BD: Apr 19, 2023).
At that time, the company said its Drove module could be retro-fitted to powered wheelchairs, allowing users “to move their chair autonomously and precisely without a joystick, to specific locations within the home - a world first”.
Today, Control Bionics said that the grant from the Arlington, Virginia-based Amyotrophic Lateral Sclerosis (ALS) Association would be used to examine the practicality of the Drove system for users, test navigation and collision avoidance, create upgrade packages for multiple wheelchair manufacturers, determine the US Food and Drug Administration regulatory requirements and secure further funding and commercialization plans.
Control Bionics chief executive officer Jeremy Steele said “the US is a key market … but also represents a large market for our autonomous wheelchair product and we are excited by the potential this award brings us”.
Control Bionics was up 0.6 cents or 12.5 percent to 5.4 cents.

ACTINOGEN MEDICAL

Actinogen says a 40-participant study of its Xanamem for Alzheimer's disease showed it had "high levels of target occupancy" in the brain at safe and biologically active doses.

In 2020, Actinogen said patient enrolment of its phase I Xanamem disease target occupancy study had been put on hold until further notice due to the Covid-19 outbreak, with most patients enrolled in the study measuring the affinity of Xanamem to bind to 11-beta-HSD-1 cortisol-activation enzyme in the brain, and it had adequate data for the detailed data analyses currently being undertaken (BD: Mar 26, 2020).

Today, the company said that 23 cognitively normal, elderly volunteers and 17 patients with Alzheimer's disease were administered Xanamem at 5mg, 10mg, 20mg or 30mg doses daily for seven days and then imaged with positron emission tomography (PET).

Actinogen said the study showed that "Xanamem achieved high target occupancy of 66 to 85 percent, which exceeded the 30 to 60 percent inhibition required for effectiveness in animal models".

Actinogen said the study confirmed that Xanamem was "a brain-penetrant inhibitor of the [target] tissue cortisol synthesis enzyme, an enzyme called 11-beta-hydroxy-steroid dehydrogenase type 1, or 11-beta-HSD-1, and had "high levels of target occupancy at doses as low as 5mg".

The research, titled 'Brain 11β-Hydroxysteroid Dehydrogenase Type 1 Occupancy by Xanamem Assessed by PET in Alzheimer's Disease and Cognitively Normal Individuals' was published in the Journal Alzheimer's disease, with an abstract available at: https://pubmed.ncbi.nlm.nih.gov/38250767/.

Actinogen said that the results were consistent with the on-going phase IIa trial of Xanamem for depression and phase IIb Alzheimer's disease trial.

Actinogen chief medical officer Dr Dana Hilt said the study "highlights just how effective Xanamem is at reaching its target enzyme in the brain".

"No other inhibitor of 11-beta-HSD-1 has ever demonstrated robust central nervous system target engagement in this way," Dr Hilt said.

"The results are consistent with our phase Ib and phase IIa clinical trial data, which showed evidence of activity on cognition in the brain with doses of 5mg and 10mg daily," Dr Hilt said.

"These same dose levels have also shown excellent safety and tolerability, and to date more than 350 people have been treated with Xanamem," Dr Hilt said.

"Oral Xanamem as a 10mg daily dose is now in phase II trials in major depressive disorder and Alzheimer's disease, with the initial phase II results in the [major depressive disorder] trial due to report [by July, 2024]," Dr Hilt said.

Actinogen was unchanged at 2.7 cents with 7.3 million shares traded.

SYNTARA (FORMERLY PHARMAXIS)

Hong Kong's Karst Peak Capital Ltd says it has ceased its substantial shareholding in Syntara with the sale of 79,450,766 shares for $1,204,700, or 1.5 cents a share.

Earlier this month, Karst Peak said that it held 79,450,766 shares in Syntara, or 9.56 percent (BD: Jan 21, 2024).

Syntara fell 0.1 cents or 5.6 percent to 1.7 cents with 1.1 million shares traded.