Biotech Daily

Thursday August 22, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRESCIENT UP 14%; AROA DOWN 13%**

*** COGSTATE REVENUE UP 7% TO $64.5m, PROFIT UP 53% TO $8m**

*** STARPHARMA REVENUE UP 132% TO $10m; LOSS DOWN 48% TO $8m**

*** NEXT SCIENCE 'REMOVES 2024 REVENUE GUIDANCE'**

*** MESOBLAST INSURERS TO PAY UNDISCLOSED LEGAL SETTLEMENT**

*** CLARITY WINS FDA FAST TRACK FOR CU-64 SAR-BIS-PSMA**

*** ZELIRA 'POSITIVE' FDA FEEDBACK FOR HOPE MARIJUANA AUTISM TRIAL**

*** OSTEOPORE, CHILE UNI FINISH PRE-CLINICAL BONE IMPLANT STUDIES**

*** IMAGION EGM FACES UP-TO 24% OPPOSITION**

*** ASX SUSPENDS AUSCANN, EPSILON ON FEES**

*** GENETIC SIGS: DR SAMARAS, DR RADFORD OUT; WALDRON, LOCKWOOD IN**

MARKET REPORT

The Australian stock market was up 0.21 percent on Thursday August 22, 2024, with the ASX200 up 16.5 points to 8,027.0 points. Fifteen of the Biotech Daily Top 40 companies were up, 20 fell and five traded unchanged.

Prescient was the best, up 0.6 cents or 13.95 percent to 4.9 cents, with 5.9 million shares traded. Opthea improved 9.9 percent; Clarity climbed 8.85 percent; Syntara was up 6.45 percent; Cynata rose 4.8 percent; SDI and Starpharma were up more than three percent; Emvision, Immutep and Orthocell improved more than two percent; Genetic Signatures, Medadvisor and Mesoblast were up more than one percent; with Avita, Cochlear, Pro Medicus and Resmed up by less than one percent.

Aroa led the falls, down 6.5 cents or 12.9 percent to 44 cents, with 5.2 million shares traded. Micro-X lost 8.6 percent; Alcidion shed 6.7 percent; Amplia and Resonance were down more than five percent; 4D Medical, Actinogen, Atomo and Paradigm fell four percent or more; Imugene was down 3.7 percent; Clinuvel, Medical Developments and Nova Eye shed more than two percent; Compumedics, Curvebeam, Neuren and Telix were down one percent or more; with CSL, Nanosonics, Polynovo and Proteomics down by less than one percent.

COGSTATE

Cogstate says revenue for the year to June 30, 2024 was up 7.4 percent to $US43,427,773 ($A64,518,000) with net profit after tax up 52.75 percent to $US5,449,884 ($A8,096,500).

Cogstate said revenue was primarily from its clinical trials contracting services, up nine percent to $US39.4 million, with sales of its cognition testing device for use in healthcare down nine percent to $US4.0 million, compared to the prior corresponding period.

The company said it continued to "win work … but Alzheimer's disease and associated dementias represent the bulk of revenue backlog" and that about 24 percent of its clinical trials services were for indications other than Alzheimer's disease.

Cogstate said in 2024-'25 it expected to see an increase in Alzheimer's trials "as supported by the contracts already executed year to date as well as ongoing customer engagement in respect of planned Alzheimer's programs".

Cogstate said diluted earnings per share was up 55.9 percent to 3.15 US cents, net tangible asset per share rose 18.2 percent to 16.01 US cents, with cash and equivalents of $US30,124,231 at June 30, 2024 compared to $US28,675,988 the prior year.

Cogstate fell 10.25 cents or nine percent to $1.0375 with 988,700 shares traded.

STARPHARMA HOLDINGS

Starpharma says revenue for the year to June 30, 2024 was up 131.8 percent to $9,756,000 with net loss after tax down 47.8 percent to $8,165,000.

Starpharma said revenue was up 182.0 percent to $8,289,000 principally due to a non-recurring $6,553,000 from the termination of its Vivagel for bacterial vaginosis (BV) agreement with Mundipharma, with the remaining revenue from interest, product sales, royalties and research revenue from commercial partners.

Starpharma said diluted loss per share fell 50 percent to two cents a share, with net tangible asset backing per share down 12.5 percent to 7.0 cents, and it had cash and equivalents of $23,360,000 at June 30, 2024 compared to $35,180,000 at June 30, 2023.

Starpharma was up 0.3 cents or 3.4 percent to 9.1 cents.

NEXT SCIENCE

Next Science says it has removed its revenue guidance of $US36 million ($A53 million) to $US40 million ($A59 million) for the year to June 30, 2024.

Next Science said in the six months to December 31, 2023 it had made "significant changes to its sales organization with the consolidation of its sales leadership, implementation of a unified strategy for its Xbio product suite and the restructuring of its [durable medical equipment] sales force and go-to-market strategy".

The company said the changes were expected to reduce yearly costs by about $US6 million "due to a more variable cost structure and led to a significant reduction in cash burn in [the three months to December 31, 2023]".

Next Science said it "recent sales results have been below expectations with the transition taking longer than originally forecast" and had removed the revenue guidance for the year "due to the uncertainty created by the sales transformation".

The company said cost reductions as a result of the sales force changes meant it expected to be cashflow positive by April 2025.

The company said it expected to be earnings before interest taxation, depreciation and amortization (Ebitda) positive "on an adjusted basis during the same period".

Next Science fell three cents or 11.8 percent to 22.5 cents.

MESOBLAST

Mesoblast says the shareholder class action filed in the Federal Court of Australia in 2022 has been resolved through an undisclosed settlement, subject to court approval.
Mesoblast said the undisclosed settlement was inclusive of costs and interest and would be "funded entirely by Mesoblast's insurers and includes no admission of liability … [and] would] have no impact on [its] cashflow or financial results".
In 2022, Mesoblast said it would "vigorously defend" a class action filed by Melbourne law firm Phi Finney McDonald in the Federal Court of Australia (BD: Jun 14, 2022).
Earlier, the company said it had been served a class action in the Federal Court by Melbourne's William Roberts Lawyers on behalf of certain shareholders who acquired an interest in the company's shares, American depository receipts, or related equity swap arrangements between February 22, 2018 and December 17, 2020 (BD: May 19, 2022).
In 2021, at least four US law firms began class actions against Mesoblast claiming it failed to inform investors of the risk of graft-versus-host disease success (BD: Oct 21, 2021).
Mesoblast was up 1.5 cents or 1.6 percent to 97.5 cents with 2.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has awarded fast track status for its copper-64 Sar-Bis-prostate specific membrane antigen (PSMA) prostate cancer test.
Clarity said FDA fast track designation was "designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs".
The company said the designation provided its copper-64 Sar-Bis-PSMA "a number of product development advantages" and paved the way "for a potentially faster review process once Clarity submits its product approval application".
Clarity said the approval meant "more frequent communication with the FDA, allowing for rapid resolution of queries during development … [and that it] can submit completed sections of its application as they are ready, rather than waiting for the entire package to be finished before it can be lodged with the FDA".
Clarity executive chair Dr Alan Taylor said the designation was "a significant milestone, especially as we are actively recruiting into our first registrational phase III trial … and preparing for an end-of-phase meeting with the FDA for a second pivotal phase III trial with this product".
Clarity was up 56 cents or 8.85 percent to $6.89 with 3.0 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has "positive feedback" from a meeting with the US Food and Drug Administration for the study design of its phase I Hope1 marijuana trial for autism.
Last year, Zelira said it had a joint venture with Cantheon Capital LLC to develop its Hope marijuana product for autism in exchange for 55 percent ownership in the company and an investment of $US8.6 million ($A12.4 million) (BD: Feb 15, 2023).
Last month, the company said it discussed the design of the phase I trial in healthy volunteers with the FDA, which would be used to open an investigational new drug application for its marijuana-based treatment with the FDA (BD: Jul 11, 2024).
Today, Zelira said following the discussion it had "clearly defined the study's target population and endpoints, specifically focusing on treating irritability associated with autism spectrum disorder in patients with Phelan-McDermid syndrome".
Zelira fell six cents or 8.1 percent to 68 cents.

OSTEOPORE

Osteopore says it has completed its pre-clinical bench and pre-verification studies of its bone implant with Santiago's Universidad de Chile (the University of Chile).

In 2022, Osteopore said it had a $US225,000 ($A352,708) grant from the Chile Government and a $US135,000 from the University of Chile to develop a three-dimensional printable implant to accelerate bone regeneration (BD: Sep 28, 2022).

At that time, the company said its current implant enabled the natural stages of bone healing and were "superior to other traditional bone regeneration procedures" but by "incorporating materials and compounds that speed up bone growth, a patients' recovery could be accelerated".

Today, Osteopore said the project had completed "the bench-testing phase with results indicating cytocompatibility".

The company said with the addition of the compound into its bone implants "osteogenic differentiation was increased over the same analysis period as baseline, indicating faster osteogenesis".

Osteopore said faster osteogenesis led to "a three-fold increase in cell adhesion of human bone lineage cells and human endothelial cells, and a 2.5-fold increase of bone-mineralizing activity, in-vitro, as compared to the baseline".

The company said the "positive results" would allow it to progress to pre-clinical studies of bone regeneration in a biological model.

Osteopore was unchanged at 4.1 cents with 3.25 million shares traded.

IMAGION BIOSYSTEMS

Imagion says its extraordinary general meeting passed all six resolutions but with between 9.61 percent and 23.89 percent opposition.

Imagion said the resolution to amend the terms of its convertible notes was opposed by 367,388 votes (23.89%) with 1,170,279 votes (76.11%).

The company said that largest number of opposition votes at the meeting were against the issue performance rights to chair Robert Proulx with 447,226 votes (12.64%) in opposition and 3,090,864 votes (87.36%) in favor.

Imagion said that the issue of performance rights to director Brett Mitchell was opposed by the same number of votes, or 14.10 percent, with 2,724,038 votes (85.90%) in support.

The company said that two resolutions to issue shares to Mercer faced 22.56 percent and 23.40 percent opposition and 9.61 percent of the meeting opposed an amendment to the company's constitution.

According to its most recent filing, Imagion company had 34,996,551 shares on offer, meaning that the 447,226 votes against the performance rights amounted to about 1.28 percent of the company, not sufficient to requisition extraordinary general meetings.

Imagion was unchanged at 3.9 cents.

AUSCANN GROUP HOLDINGS, EPSILON HEALTHCARE

The ASX says it has suspended Auscann and Epsilon from quotation for not paying its annual listing fees by the August 21, 2024 deadline, under Listing Rule 17.6.

Auscann last traded at four cents.

Epsilon last traded at 2.4 cents.

GENETIC SIGNATURES

Genetic Signatures says director Caroline Waldron will replace chair Dr Nick Samaras on November 20, 2024, with Anne Lockwood to replace director Dr Tony Radford.

Genetic Signatures said Dr Samaras intended to resign at its annual general meeting, following 16 years as chair.

The company said Dr Samaras had “guided the company through its transformation from a research-based organization to a fully-fledged commercial company with revolutionary molecular diagnostic products approved in multiple markets around the globe”.

Genetic Signatures said Dr Radford had retired, effective immediately “in order to reduce his work commitments and focus on personal and family activities” following nine years as a director.

The company said Ms Lockwood was a non-executive director of Mayne Pharma and chief financial officer of Planet Innovation, with her appointment effective from October 1, 2024.

According to her Linkedin profile, Ms Lockwood held a Bachelor of Commerce from Melbourne’s Deakin University.

Genetic Signatures was up one cent or 1.4 percent to 71 cents.