Alector Reports Second Quarter 2024 Financial Results and Provides Business Update

August 7, 2024

Data from INVOKE-2 Phase 2 clinical trial of AL002 in individuals with early Alzheimer's disease (AD) on track for Q4 2024

Patient baseline characteristics data for the INVOKE-2 trial confirm the intended study population for testing the effects of AL002, a novel TREM2 agonist, in early AD

The latozinemab pivotal INFRONT-3 Phase 3 trial continues to progress well, supported by a recent U.S. Food and Drug Administration interaction post Breakthrough Therapy Designation

$503.3 million in cash, cash equivalents and investments provide runway through 2026

Management to host conference call and webcast today at 4:30 p.m. ET/1:30 p.m. PT

SOUTH SAN FRANCISCO, Calif., Aug. 07, 2024 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported second quarter 2024 financial results and recent portfolio and business updates. As of June 30, 2024, Alector's cash, cash equivalents and investments totaled $503.3 million.

"Alector's significant progress in recent months has set the stage for a transformative period ahead, as we approach key clinical catalysts for our maturing, potential first-in-class immuno-neurology programs," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "We remain on track to report data from INVOKE-2, our Phase 2 clinical trial in early Alzheimer's disease for AL002, in the fourth quarter, and we are encouraged that the recently reported patient baseline characteristics reflect a study population appropriate for the clinical evaluation of a TREM2 agonist in this indication."

Dr. Rosenthal continued, "In addition, the recent Breakthrough Therapy Designation for latozinemab in frontotemporal dementia with a progranulin gene mutation has provided the opportunity for increased interactions with the FDA about this program, and we now have additional clarity on how key biomarkers may support our path to a potential regulatory submission. In parallel, we are continuing to enroll patients in the PROGRESS-AD Phase 2 trial of AL101/GSK4527226. With a cash runway that extends through 2026, we are in a strong financial position as we approach these key milestones."

Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development at Alector added, "In June, Alector hosted a virtual research and development event focused on the Alector Brain Carrier (ABC), our proprietary, versatile blood-brain barrier technology. We believe our ABC technology platform has the potential to deliver novel drugs safely into the CNS, enabling potential best-in-class therapeutics for patients suffering from neurological disorders. We look forward to providing updates on our progress in the future."

Recent Clinical Updates

Immuno-Neurology Portfolio
Progranulin Programs (latozinemab (AL001) and AL101/GSK4527226) Being Developed in Collaboration with GSK

- In a recent Type B interaction with the U.S. Food and Drug Administration (FDA), Alector and GSK received feedback on the potential future Biologics License Application (BLA) for latozinemab targeting frontotemporal dementia with a progranulin gene mutation (FTD-*GRN*). The FDA has indicated that it would consider the effects of latozinemab on plasma and cerebrospinal fluid concentrations of progranulin (PGRN) as confirmatory evidence, supplementing the potential clinical effects of latozinemab in FTD-*GRN*, pending BLA review. The companies also aligned with the agency on disease-relevant fluid and imaging biomarkers that may be considered as supportive evidence of clinical efficacy, subject to BLA review. These include biomarkers of astrocyte function, neurodegeneration, and brain atrophy. Based on the FDA feedback, Alector and GSK remain confident that the totality of evidence, including the primary clinical endpoint and biomarkers, could provide a path to potential approval for latozinemab. The Type B interaction occurred after the FDA granted Breakthrough Therapy Designation to latozinemab for the potential treatment of FTD-*GRN* earlier this year.
- The pivotal, randomized, double-blind, placebo-controlled INFRONT-3 Phase 3 clinical trial of latozinemab in FTD-*GRN* is ongoing. Enrollment was completed in October 2023, and the treatment duration is 96 weeks. INFRONT-3 is evaluating the safety and efficacy of latozinemab in slowing disease progression in individuals with FTD-*GRN*. The primary endpoint in INFRONT-3 is disease progression as measured by the Clinical Dementia Rating scale plus National Alzheimer's Disease Coordinating Center Frontotemporal Lobar Degeneration Sum of Boxes (CDR® plus NACC FTLD-SB). The trial also employs other clinical and functional outcome assessments.
- Alector plans to present the poster "Baseline characteristics for INFRONT-3: A Phase 3, double-blind, placebo-controlled 96-week study evaluating latozinemab in FTD-*GRN*" at the International Society for Frontotemporal Dementias (ISFTD) in Amsterdam from September 19-22, 2024.
- Enrollment is ongoing in the PROGRESS-AD global Phase 2 clinical trial of AL101/GSK4527226 in early Alzheimer's disease (AD). Alector and GSK are co-developing AL101 for the potential treatment of more prevalent neurodegenerative diseases, including AD and Parkinson's disease.

- In July 2024, Alector and GSK presented posters highlighting PGRN and AL101 at the Alzheimer's Association International Conference® 2024 (AAIC®). The presentations included data supporting the therapeutic hypothesis of increasing PGRN levels for the potential treatment of AD and the design of the ongoing PROGRESS-AD Phase 2 clinical trial.

TREM2 Program (AL002) Being Developed in Collaboration with AbbVie

- The INVOKE-2 Phase 2 clinical trial of AL002 is fully enrolled, and data from the trial are anticipated in the fourth quarter of 2024. INVOKE-2, a randomized, double-blind, placebo-controlled, dose-ranging study, is designed to evaluate the efficacy and safety of AL002 in slowing disease progression in individuals with early AD. AL002 is a novel investigational humanized monoclonal antibody that binds to TREM2 to increase TREM2 signaling and, thereby, is hypothesized to improve the functionality of microglia. It is the most advanced TREM2-activating product candidate in clinical development worldwide.
- At AAIC® in July 2024, Alector presented data highlighting the patient baseline characteristics for the INVOKE-2 study. The data confirm the intended study population for testing the effects of AL002, a novel TREM2 agonist, in early AD. Of note, for those participants with amyloid PET assessed at baseline, the mean (standard deviation) in centiloids was 100.1 (38.9), consistent with expectations for an early AD population in INVOKE-2. In a separate poster, Alector also presented data supporting the use of a blood-based amyloid test for screening AD patients eligible for participation in the INVOKE-2 trial.
- AbbVie has an exclusive option to globally develop and commercialize AL002, upon receipt and evaluation of the INVOKE-2 data. AbbVie's exercise of that option would prompt a $250 million payment to Alector.

Early Research Pipeline

- Alector is actively progressing its Alector Brain Carrier (ABC), a proprietary, versatile blood-brain barrier (BBB) technology platform, which is being applied selectively to the company's next-generation product candidates and research pipeline. Initial work has focused on transferrin receptor (TfR) and CD98hc targets, which have distinct expression profiles and cellular trafficking pathways but have both been shown to be highly expressed at the BBB and able to drive brain uptake when utilized as transcytosis receptors.
- In June 2024, Alector hosted a virtual research and development event discussing the company's ABC technology platform in detail. The event included a presentation from Dr. Zhiqiang An, Ph.D., Professor & Robert A. Welch Distinguished University Chair in Chemistry and Director of the Texas Therapeutics Institute at UTHealth Houston, who provided insights into emerging technologies for BBB modulation and discussed future directions and opportunities in the field.

Second Quarter 2024 Financial Results

Revenue. Collaboration revenue for the quarter ended June 30, 2024, was $15.1 million, compared to $56.2 million for the same period in 2023. The decrease was mainly due to a $35.7 million decrease in revenue recognized for the AL101 programs, including a cumulative non-cash revenue adjustment due to a contract modification in the second quarter of 2023 to have GSK operationalize the AL101 Phase 2 study. The decrease is partially due to a $15.2 million decrease in revenue recognized for the AL002 program due to the addition of AL002 LTE and patient replacement revenue in 2023. This was offset by a $9.8 million increase in revenue recognized for the latozinemab programs.

R&D Expenses. Total research and development expenses for the quarter ended June 30, 2024, were $46.3 million, compared to $46.2 million for the quarter ended June 30, 2023. The increase was mainly driven by the Company's prioritization on selected late-stage programs.

G&A Expenses. Total general and administrative expenses for the quarter ended June 30, 2024, were $14.4 million, compared to $13.6 million for the quarter ended June 30, 2023.

Net Income (Loss). For the quarter ended June 30, 2024, Alector reported a net loss of $38.7 million, or $0.40 per share, compared to a net income of $1.4 million, or $0.02 net income per share, for the same period in 2023.

Cash Position. Cash, cash equivalents, and investments were $503.3 million as of June 30, 2024. Management expects that this will be sufficient to fund current operations through 2026.

2024 Guidance. The Company continues to anticipate collaboration revenue to be between $60 million and $70 million. Management has updated its total research and development expenses to be between $210 million and $220 million and reiterated total general and administrative expenses to be between $60 million and $70 million.

Second Quarter 2024 Conference Call

Alector's management team will host a conference call discussing Alector's results for the second quarter of 2024 and provide a business update. The conference call will be webcast and accessible via the investor relations section of Alector's website at www.alector.com.

To access the call, please use the following information:

Date: Wednesday, August 7, 2024
Time: 4:30 p.m. ET, 1:30 p.m. PT

The event will be webcast live under the investor relations section of Alector's website at https://investors.alector.com/events-and-presentations/events, and following the event, a replay will be archived there for 30 days. Interested parties participating by phone will need to register using this

online form. After registering for dial-in details, all phone participants will receive an auto-generated e-mail containing a link to the dial-in number along with a personal PIN number to use to access the event by phone.

About Alector

Alector is a clinical-stage biotechnology company pioneering immuno-neurology, a novel therapeutic approach for the treatment of neurodegenerative diseases. Immuno-neurology targets immune dysfunction as a root cause of multiple pathologies that are drivers of degenerative brain disorders. Alector has discovered and is developing a broad portfolio of innate immune system programs, designed to functionally repair genetic mutations that cause dysfunction of the brain's immune system and enable rejuvenated immune cells to counteract emerging brain pathologies. Alector's immuno-neurology product candidates are supported by biomarkers and seek to treat indications, including Alzheimer's disease and genetically defined frontotemporal dementia patient populations. Alector is headquartered in South San Francisco, California. For additional information, please visit www.alector.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements regarding our business plans, business strategy, product candidates, blood-brain barrier technology platform, planned and ongoing preclinical studies and clinical trials, anticipated timing of and detail regarding release of data for INVOKE-2 and INFRONT-3, expected milestones, expectations of our collaborations, expectations of our interactions with regulatory authorities, and financial and cash guidance. Such statements are subject to numerous risks and uncertainties, including but not limited to risks and uncertainties as set forth in Alector's Quarterly Report on Form 10-Q filed on August 7, 2024, with the Securities and Exchange Commission ("SEC"), as well as the other documents Alector files from time to time with the SEC. These documents contain and identify important factors that could cause the actual results for Alector to differ materially from those contained in Alector's forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and Alector specifically disclaims any obligation to update any forward-looking statement, except as required by law.

Selected Consolidated Balance Sheet Data
(in thousands)

	June 30, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 503,334	$ 548,861
Total assets	570,729	621,827
Total current liabilities (excluding deferred revenue)	83,721	94,973
Deferred revenue (including current portion)	263,544	293,820
Total liabilities	420,162	487,669
Total stockholders' equity	150,567	134,158

Consolidated Statement of Operations Data
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 15,083	$ 56,214	$ 30,976	$ 72,763
Operating expense:				
Research and development	46,314	46,177	91,481	98,064
General and administrative	14,375	13,626	28,809	28,403
Total operating expenses	60,689	59,803	120,290	126,467
Loss from operations	(45,606)	(3,589)	(89,314)	(53,704)
Other income, net	7,003	6,357	14,639	11,516
Income (loss) before income tax	(38,603)	2,768	(74,675)	(42,188)
Income tax expense	73	1,393	80	2,294
Net income (loss)	$ (38,676)	$ 1,375	$ (74,755)	$ (44,482)
Net income (loss) per share:				
Net income (loss) per share, basic	$ (0.40)	$ 0.02	$ (0.78)	$ (0.53)
Net income (loss) per share, diluted	$ (0.40)	$ 0.02	$ (0.78)	$ (0.53)
Weighted averages shares used in calculating:				
Shares used in computing net income (loss) per share, basic	96,674,921	83,497,125	95,242,548	83,186,052
Shares used in computing net income (loss), per shares, diluted	96,674,921	83,566,293	95,242,548	83,186,052

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