Alector Reports Third Quarter 2024 Financial Results and Provides Business Update

November 6, 2024

Data from INVOKE-2, evaluating TREM2 agonist candidate AL002 in patients with early Alzheimer's disease (AD), on track for 2024

Participant baseline characteristics in pivotal INFRONT-3 Phase 3 trial suggest a representative study population for testing the effects of latozinemab in frontotemporal dementia with a progranulin gene mutation (FTD-GRN)

$457.2 million in cash, cash equivalents and investments provide runway through 2026

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported third quarter 2024 financial results and recent portfolio and business updates. As of September 30, 2024, Alector's cash, cash equivalents, and investments totaled $457.2 million.

"We continue to make meaningful progress advancing our innovative pipeline of product candidates and remain on track to report data in 2024 from the INVOKE-2 Phase 2 trial of AL002, the most advanced TREM2 candidate in clinical development for early Alzheimer's disease," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "We believe that increased TREM2 signaling via AL002 may recruit disease-fighting microglia to broadly counteract the progression of Alzheimer's disease. INVOKE-2 is designed to provide meaningful insights into AL002's potential benefits across a combination of clinical and functional endpoints, as well as imaging and fluid biomarkers. We also believe that the broad mechanism of AL002 may have the potential to deliver potent and durable therapeutic benefits, both as a standalone therapy and in combination with anti-amyloid beta antibodies."

Dr. Rosenthal continued, "For our progranulin franchise, we recently reported the patient baseline characteristics for our INFRONT-3 Phase 3 clinical trial of latozinemab in frontotemporal dementia with a progranulin gene mutation, suggesting a representative study population in this indication. We are approaching a top-line data readout for INFRONT-3 in late 2025/early 2026. Additionally, PROGRESS-AD, the Phase 2 trial of AL101/GSK4527226 in early Alzheimer's disease, has reached more than one-third of its target enrollment. It is an exciting time at Alector, and we are well positioned to advance our proprietary pipeline of novel immuno-neurology drugs."

Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development at Alector, added, "We are actively advancing our Alector Brain Carrier, ABC, a proprietary versatile blood-brain barrier technology, and we are strategically leveraging this platform across our portfolio. We believe our ABC technology may advance treatment of neurodegenerative diseases by potentially enabling improved delivery of our therapeutics to the brain."

Recent Clinical Updates

Immuno-Neurology Portfolio
TREM2 Program (AL002) Being Developed in Collaboration with AbbVie

- The results of the INVOKE-2 Phase 2 clinical trial of AL002 are expected in 2024. INVOKE-2, a randomized, double-blind, placebo-controlled, dose-ranging study, is designed to assess the efficacy and safety of AL002 in slowing disease progression in individuals with early Alzheimer's disease (AD). AL002 is a novel investigational humanized monoclonal antibody (mAb) that is designed to bind to TREM2 to increase TREM2 signaling and, thereby, is hypothesized to improve the functionality of microglia. It is the most advanced TREM2 agonist product candidate in clinical development worldwide.
- 98% of eligible participants who completed the planned treatment period of INVOKE-2 have elected to participate in the long-term extension (LTE) study.
- In October 2024, Alector published a manuscript titled "Preclinical and first-in-human evaluation of AL002, a novel TREM2 agonistic antibody for Alzheimer's disease" in *Alzheimer's Research & Therapy.* The publication outlines preclinical and INVOKE-1 Phase 1 study results, demonstrating that AL002 engaged TREM2, and induced pharmacodynamic biomarker changes associated with microglial proliferation, survival, and phagocytic activity in a dose-dependent manner.
- AbbVie has an exclusive option to globally develop and commercialize AL002. Alector will deliver a data package resulting from the INVOKE-2 study to AbbVie for their evaluation. AbbVie's exercise of its option would prompt a $250 million payment to Alector.

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

- The pivotal, randomized, double-blind, placebo-controlled INFRONT-3 Phase 3 clinical trial of latozinemab targeting frontotemporal dementia with a progranulin gene mutation (FTD-*GRN*) is ongoing and on track, with enrollment completed in October 2023 and a treatment duration of 96 weeks. Latozinemab is a novel investigational human mAb that aims to increase progranulin (PGRN) levels by inhibiting sortilin and is the most advanced PGRN-elevating candidate in development for the treatment of FTD-*GRN*.

- In September 2024, Alector presented a poster highlighting the patient baseline characteristics for INFRONT-3 at the 14th International Conference on Frontotemporal Dementias (ISFTD 2024). Notably, the baseline characteristics of symptomatic INFRONT-3 participants, including age, Clinical Dementia Rating scale plus National Alzheimer's Disease Coordinating Center Frontotemporal Lobar Degeneration Sum of Boxes (CDR® plus NACC FTLD-SB) score and neurofilament light chain (NfL) levels, were representative of the broader FTD-*GRN* registry population, based on available registry data. Additionally, Alector shared findings from the FTD Caregiver Survey and FTD Insights Survey, highlighting the challenges faced by caregivers of individuals living with FTD.

- PROGRESS-AD, a global, randomized, double-blind, placebo-controlled Phase 2 clinical study evaluating AL101/GSK4527226 in early AD has reached more than one-third of its target enrollment of 282 participants, with dosing initiated in February 2024. AL101 is an investigational human mAb designed to block and downregulate the sortilin receptor to elevate the level of PGRN in the brain in a manner that is similar to investigational latozinemab but with different pharmacokinetic and pharmacodynamic properties.

Early Research Pipeline

- Alector continues to advance its Alector Brain Carrier (ABC), a proprietary, versatile blood-brain barrier technology platform, which is being applied selectively to the company's next-generation product candidates and research pipeline. The technology platform enables customization of affinity, valency, and format to optimize effector function and half-life in preclinical models. Alector is applying its ABC technology, combined with its expertise in immuno-neurology, to work on novel targets and develop first or best-in-class therapeutics.

Third Quarter 2024 Financial Results

Revenue. Collaboration revenue for the quarter ended September 30, 2024, was $15.3 million, compared to $9.1 million for the same period in 2023. The increase was mainly due to an increase in revenue recognized for the AL002 program.

R&D Expenses. Total research and development expenses for the quarter ended September 30, 2024, were $48.0 million, compared to $46.3 million for the quarter ended September 30, 2023. The increase was mainly driven by the increase in research and development expenses for the AL101 programs resulting from the initiation of the PROGRESS-AD Phase 2 clinical trial in 2024.

G&A Expenses. Total general and administrative expenses for the quarter ended September 30, 2024, were $15.8 million, compared to $13.4 million for the quarter ended September 30, 2023. The increase was mainly due to the impairment of the right-of-use asset and the leasehold improvements as the Company transitioned operations from its laboratory and office space in Newark to its South San Francisco headquarters.

Net Loss. For the quarter ended September 30, 2024, Alector reported a net loss of $42.2 million, or $0.43 per share, compared to a net loss of $44.5 million, or $0.53 per share, for the same period in 2023.

Cash Position. Cash, cash equivalents, and investments were $457.2 million as of September 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, total research and development expenses to be between $210 million and $220 million, and total general and administrative expenses to be between $60 million and $70 million.

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 November 6, 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)

	September 30,	**December 31,**

	2024	2023
Cash, cash equivalents, and marketable securities	$ 457,202	$ 548,861
Total assets	516,023	621,827
Total current liabilities (excluding deferred revenue)	87,098	94,973
Deferred revenue (including current portion)	248,202	293,820
Total liabilities	397,090	487,669
Total stockholders' equity	118,933	134,158

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 15,342	$ 9,109	$ 46,318	$ 81,872
Operating expense:				
Research and development	47,998	46,328	139,479	144,392
General and administrative	15,778	13,364	44,587	41,767
Total operating expenses	63,776	59,692	184,066	186,159
Loss from operations	(48,434)	(50,583)	(137,748)	(104,287)
Other income, net	6,214	7,360	20,853	18,876
Net loss before income tax	(42,220)	(43,223)	(116,895)	(85,411)
Income tax expense	—	1,252	80	3,546
Net loss	$ (42,220)	$ (44,475)	$ (116,975)	$ (88,957)
Net loss per share:				
Net loss per share, basic and diluted	$ (0.43)	$ (0.53)	$ (1.22)	$ (1.07)
Shares used in computing net loss per share basic and diluted	97,519,595	83,927,961	96,007,105	83,513,954

Alector Contacts:

Alector
Katie Hogan
202-549-0557
katie.hogan@alector.com

1AB (media)
Dan Budwick
973-271-6085
dan@1abmedia.com

Argot Partners (investors)
Laura Perry
212-600-1902
alector@argotpartners.com

Source: Alector, Inc.