Alector Reports Third Quarter 2022 Financial Results and Provides Business Update

November 8, 2022

Progressing enrollment in the INFRONT-3 Phase 3 pivotal study for latozinemab (AL001) and in the INVOKE-2 Phase 2 study for AL002

Initiated first-in-human Phase 1 trial of AL044, the company's third novel, first-in-class clinical stage microglia immune checkpoint therapy for the treatment of Alzheimer's disease (AD)

$758.3 million in cash, cash equivalents and investments provide runway through 2024

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology and innate immuno-oncology, today reported third quarter 2022 financial results and recent portfolio and business updates. As of September 30, 2022, Alector's cash, cash equivalents and investments totaled $758.3 million.

Commentary on the Quarter:

"In the third quarter, we expanded our first-in-class clinical immuno-neurology pipeline with AL044, a biologic targeting *MS4A,* a brain immune checkpoint molecule and a genetic risk factor for Alzheimer's disease. We also continued to advance our INFRONT-3 Phase 3 pivotal study of latozinemab for frontotemporal dementia with progranulin mutations, or FTD-*GRN,* and our INVOKE-2 Phase 2 Alzheimer's disease study with AL002, which activates TREM2 receptor signaling," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "We will be reporting new data from the Phase 1 study of AL101 later this year at CTAD in addition to follow-up data from the INFRONT-2 Phase 2 trial in patients with symptomatic FTD-*C9orf72* in 2023."

"We anticipate biomarker data from the AL044 healthy volunteer study and completion of enrollment in our INVOKE-2 study in 2023. We believe that our immuno-neurology drug candidates, which are designed to regulate key aspects of microglial proliferation, survival, migration, lysosomal function and immune response, could prove important in effectively treating neurodegeneration either as stand-alone therapies or potentially in combination with anti-beta amyloid drugs."

Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development at Alector, added, "Our immuno-oncology pipeline continues to advance as well. We remain on track to submit an IND for AL009, Alector's first-in-class multi-Siglec inhibitor, by the end of the year."

"We are also thrilled to have expanded our talented leadership team over the past quarter as we welcomed Peter Heutink, Ph.D., as Chief Scientific Officer," said Dr. Kenkare-Mitra. "Peter's expertise in the human genetics of neurodegenerative disease is important to our efforts at Alector."

Clinical Programs

Immuno-Neurology Portfolio
Progranulin Assets (Latozinemab, AL101)

- Enrollment is ongoing globally in the INFRONT-3 randomized, placebo-controlled, pivotal Phase 3 trial evaluating the efficacy and safety of latozinemab (AL001) in at-risk and symptomatic patients with FTD-*GRN*. The first patient has been enrolled in the open-label extension study.

- The company expects to report follow-up data from the INFRONT-2 Phase 2 clinical trial of latozinemab in frontotemporal dementia patients with a *C9orf72* genetic mutation (FTD-*C9orf72*) in 2023.

- Alector will present a poster, *Repeat IV and SC dosing of the Anti-Sortilin Antibody AL101*, with data from the Phase 1 trial of AL101 in healthy volunteers at the 15th Clinical Trials on Alzheimer's Disease (CTAD) conference, being held in San Francisco, California from November 29 to December 2, 2022. AL101 is intended to elevate progranulin levels in a manner similar to latozinemab, and the company plans to investigate AL101 for the treatment of Alzheimer's disease (AD) and Parkinson's disease (PD).

- Latozinemab and AL101 are being developed in collaboration with GSK.

TREM2 Asset (AL002)

- Enrollment in the INVOKE-2 Phase 2 study of AL002 continues. The INVOKE-2 Phase 2 clinical trial is designed to evaluate the efficacy and safety of AL002 in slowing disease progression in individuals with early AD. AL002 is being developed in collaboration with AbbVie and targets Triggering Receptor Expressed on Myeloid cells 2 (TREM2) to increase TREM2 signaling and the functionality of microglia, which are brain-specific immune cells.

Novel MS4A Asset (AL044)

- The company commenced its first-in-human Phase 1 trial of AL044, the first clinical-stage drug candidate to target *MS4A*, a major genetic risk factor for AD and an immune checkpoint expressed on microglia. The study, initiated in September of this year, is investigating the safety profile, pharmacokinetics (PK), pharmacodynamics (PD) and target engagement of AL044 in healthy adults. Safety and biomarker data from this study are anticipated in 2023. The company views *MS4A* as a master inhibitory checkpoint for the brain's immune system and believes its inhibition will activate microglia in a disease-selective manner to broadly counteract Alzheimer's disease and potentially orphan neurodegenerative indications.

Immuno-Oncology Portfolio
Multi-Siglec and SIRPα Assets (AL009, AL008)

- Alector anticipates submitting an IND for its AL009 innate immuno-oncology program before the end of the year. The company will present a poster, *Characterization of suppressive myeloid cells in solid tumors to refine disease selection in a Phase 1 study of the multi-Siglec inhibitor AL009,* at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting being held in Boston, Massachusetts and virtually from November 8 to 12, 2022. AL009 is a dual function biologic that inhibits multiple Siglec receptors on myeloid cells and simultaneously activates a stimulating receptor on the same cells. The company plans to prioritize tumor types that have immunosuppressive phenotypes and expects to study AL009 as a monotherapy and in combination with standard of care.

- The company plans to utilize data and documentation from a regulatory filing previously submitted by Innovent to Chinese authorities for AL008 to support a potential IND submission in the U.S. AL008 is a novel innate immuno-oncology candidate with a dual mechanism of action, targeting SIRP-alpha (*SIRP*α) to inhibit the CD47- *SIRP*α pathway and activating Fc receptors to promote immuno-stimulatory pathways that drive anti-tumor immunity.

Recent Corporate Updates

- Peter Heutink, Ph.D., began his role as Alector's Chief Scientific Officer in October. Leveraging nearly 30 years of experience in the neurodegenerative disease space, Dr. Heutink provides scientific oversight of the company's significant research pipeline and helps drive business strategy.

Third Quarter 2022 Financial Results

Revenue. Collaboration revenue for the quarter ended September 30, 2022, was $14.9 million, compared to $182.4 million for the same period in 2021. The decrease of $167.6 million was due to $173.4 million collaboration revenue recognized from AL001 FTD-*GRN* license provided as part of the GSK Agreement in 2021.

R&D Expenses. Total research and development expenses for the quarter ended September 30, 2022, were $48.3 million, compared to $43.1 million for the quarter ended September 30, 2021. The increase in R&D expenses was mainly driven by increased personnel-related expenses as well as an increase in AL002 expenses.

G&A Expenses. Total general and administrative expenses for the quarter ended September 30, 2022, were $14.3 million, compared to $13.0 million for the same period in 2021. The increase is primarily due to personnel-related expenses.

Net Income (Loss). For the quarter ended September 30, 2022, Alector reported net loss of $46.1 million, or $0.56 net loss per share, compared to a net income of $126.6 million, or $1.56 net income per share, for the same period in 2021.

Cash Position. Cash, cash equivalents, and investments were $758.3 million as of September 30, 2022. Management anticipates that this will be sufficient to fund current operations through 2024.

About Alector
Alector is a clinical-stage biotechnology company pioneering immuno-neurology, a novel therapeutic approach for the treatment of neurodegenerative diseases, and innate immuno-oncology. 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 target genetically defined patient populations in frontotemporal dementia and Alzheimer's disease. This scientific approach is also the basis for the company's innate immuno-oncology programs. 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, planned preclinical studies, clinical trials, expected milestones, expectations of our collaborations, 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, as filed on November 8, 2022, 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, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 758,306	$ 735,251
Total assets	837,038	814,658
Total current liabilities (excluding deferred revenue)	41,205	48,752
Deferred revenue (including current portion)	506,041	425,218
Total liabilities	583,934	513,934
Total stockholders' equity	253,104	300,724

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 14,852	$ 182,413	$ 119,177	$ 193,091
Operating expense:				
Research and development	48,348	43,066	155,925	136,617
General and administrative	14,252	13,018	45,648	38,015
Total operating expenses	62,600	56,084	201,573	174,722
Income (loss) from operations	(47,748)	126,329	(82,396)	18,369
Other income, net	2,333	268	4,047	910
Net income (loss) before income tax	(45,415)	126,597	(78,349)	19,279
Income tax expense	733		2,533	
Net income (loss)	$ (46,148)	$ 126,597	$ (80,882)	$ 19,279
Net income (loss) per share:				
Basic net income (loss) per share	$ (0.56)	$ 1.56	$ (0.98)	$ 0.24
Diluted net income (loss) per share	$ (0.56)	$ 1.49	$ (0.98)	$ 0.23
Weighted-average shares used in calculating:				
Basic net income (loss) per share	82,602,842	80,964,701	82,367,936	80,048,758
Diluted net income (loss) per share	82,602,842	85,232,690	82,367,936	82,871,254

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