Alector Reports First Quarter 2023 Financial Results and Provides Business Update

May 4, 2023

On track to engage with regulatory authorities on the pivotal Phase 3 INFRONT-3 clinical trial of latozinemab in mid-2023; targeting data readout in early 2025

Plan to present additional results from the entire FTD-C9orf72 cohort in the INFRONT-2 Phase 2 clinical trial of latozinemab during the second half of 2023

Anticipate completing enrollment in the INVOKE-2 Phase 2 clinical trial of AL002 in patients with early Alzheimer's disease in Q3 2023, with data readout expected by Q4 2024

$669.3 million in cash, cash equivalents and investments provide runway through 2025

SOUTH SAN FRANCISCO, Calif., May 04, 2023 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported first quarter 2023 financial results and recent portfolio and business updates. As of March 31, 2023, Alector's cash, cash equivalents and investments totaled $669.3 million.

"We continue the momentum built in 2022, making steady progress in the first quarter advancing our late-stage immuno-neurology programs," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "We remain on track to engage with regulatory authorities this summer regarding the INFRONT-3 trial of latozinemab, and we are targeting early 2025 for a data readout from the pivotal trial. As we look ahead to the remainder of 2023, we anticipate important milestones across our pipeline, including completing enrollment in the Phase 2 clinical trial of our TREM2 candidate, AL002, in patients with early Alzheimer's disease and new data from the INFRONT-2 clinical trial of latozinemab in FTD- *C9orf72*. I look forward to providing updates on our late-stage clinical and early research programs in the coming months."

Gary Romano, M.D., Ph.D., Chief Medical Officer of Alector added, "We have an exciting year ahead of us as we continue to progress latozinemab, AL101 and AL002 through the clinic. We are very encouraged by recent drug development programs in neurological disorders that have successfully leveraged treatment effects on biomarkers to support clinical efficacy. All our clinical studies are designed to deliver robust biomarker and clinical data that will evaluate the therapeutic effects of our antibody candidates on disease pathophysiology and clinical disease progression. In our Phase 2 INFRONT-2 trial of latozinemab, we have observed normalization of CSF and plasma levels of GFAP. Increased levels of GFAP are associated with faster rates of brain atrophy in FTD. We look forward to sharing additional data from the FTD-*C9orf72* cohort later this year, and we continue to advance our pivotal Phase 3 INFRONT-3 study, which evaluates those biomarkers and clinical endpoints in a double-blinded, randomized, placebo-controlled trial of latozinemab for the treatment of FTD-*GRN*."

Recent Clinical Updates

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

- Alector is preparing to engage with regulatory authorities in mid-2023 to discuss statistical analysis plans for the pivotal Phase 3 INFRONT-3 clinical trial evaluating the efficacy and safety of latozinemab (AL001) in patients with frontotemporal dementia due to a progranulin gene mutation (FTD-*GRN*). Emerging knowledge in the field may enable completion of the study with fewer patients and/or a shorter treatment duration. The company is targeting an INFRONT-3 data readout in early 2025 with the potential for a Biologics License Application (BLA) filing in late 2025 subject to regulatory discussion outcomes.

- As previously announced, Alector plans to present additional data from the INFRONT-2 Phase 2 clinical trial of latozinemab in FTD-*C9orf72* during the second half of 2023. The data is expected to include additional results from the entire FTD-*C9orf72* cohort. To date, the company has presented 12-month results from six symptomatic *FTD-C9orf72* trial participants treated with latozinemab. The FTD-*C9orf72* cohort represents the first clinical dataset in an indication where latozinemab elevated progranulin above physiological levels, supporting the company's efforts to expand the progranulin franchise into additional neurodegenerative disease indications, including Alzheimer's disease (AD), Parkinson's disease (PD) and amyotrophic lateral sclerosis (ALS).

- The company submitted a poster, *PK/PD modeling of progranulin elevation in blood and CSF to support AL101 dose selection and Phase 2 study design*, for the 2023 Annual Meeting of the American College of Clinical Pharmacology (ACCP) being held in Bellevue, Washington from September 10-12, 2023. The pharmacokinetic and pharmacodynamic (PK/PD) modeling supports dose selection for the Phase 2 study of AL101 in AD. AL101 is intended to elevate progranulin levels in a manner similar to latozinemab but with different PK/PD properties, and the company plans to investigate AL101 for the treatment of AD and PD. As previously reported, Alector and GSK plan to initiate a global Phase 2 clinical trial with AL101 in early AD.

TREM2 Program (AL002) Being Developed in Collaboration with AbbVie

- Alector received a $17.8 million milestone payment from AbbVie in March 2023 after enrolling and dosing the first patient in a long-term extension (LTE) of the INVOKE-2 Phase 2 clinical trial in patients with early AD. Alector may also receive up to an additional $12.5 million from AbbVie to support enrollment in the INVOKE-2 trial. Alector is on track to complete enrollment in the trial in the third quarter of 2023, with top-line data expected by the fourth quarter of 2024. The INVOKE-2 trial is designed to evaluate the efficacy and safety of AL002 in slowing disease progression in individuals with early AD.

- AbbVie has an exclusive option to globally develop and commercialize AL002. AbbVie's exercise of that option would prompt a $250 million payment to Alector.

Early Research Pipeline

- Alector continues to strategically invest in and advance its innovative research portfolio to fuel its development pipeline. The company's target discovery engine robustly integrates functional genomics, external and internal data, and machine learning. Additionally, the company is applying its proprietary blood brain barrier technologies to support its next-generation product candidates.

Recent Corporate Updates

- Kristina Cutter, M.P.H., was promoted to Chief Regulatory, Pharmacovigilance, and Quality Assurance Officer. Ms. Cutter has over 20 years of biotechnology industry experience and oversees the global regulatory and safety strategy as well as Alector's quality systems, which ensure the right to operate across Alector's immuno-neurology portfolios.

First Quarter 2023 Financial Results

Revenue. Collaboration revenue for the quarter ended March 31, 2023, was $16.5 million, compared to $24.5 million for the same period in 2022. This decrease was primarily due to less revenue recognized from the GSK agreement.

R&D Expenses. Total research and development expenses for the quarter ended March 31, 2023, were $51.9 million, compared to $53.0 million for the same period in 2022. The decrease in R&D expenses was mainly driven by the decrease in our latozinemab programs due to the timing of manufacturing activities offset by an increase in the AL002 program due to higher enrollment activities and the addition of the LTE trial.

G&A Expenses. Total general and administrative expenses for the quarter ended March 31, 2023, were $14.8 million, compared to $15.6 million for the same period in 2022 mainly driven by a decrease in consulting expenses related to accounting, recruiting, IT, and other general expenses.

Net Loss. For the quarter ended March 31, 2023, Alector reported a net loss of $45.9 million, or $0.55 per share, compared to a net loss of $44.6 million, or $0.54 per share, for the same period in 2022.

Cash Position. Cash, cash equivalents, and investments were $669.3 million as of March 31, 2023. Management expects that this will be sufficient to fund current operations through 2025.

2023 Guidance. Management anticipates, for the year ending 2023, collaboration revenue to be between $15 million and $25 million, total research and development expenses to be between $225 million and $245 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 target genetically defined patient populations in frontotemporal dementia and Alzheimer's disease. 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 and ongoing preclinical studies and clinical trials, expected milestones, including the proposed timing on engagement with regulatory authorities for certain product candidates, 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 filed on May 4, 2023 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)

	March 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 669,329	$ 712,851
Total assets	748,342	787,648
Total current liabilities (excluding deferred revenue)	37,527	45,578
Deferred revenue (including current portion)	492,852	491,601
Total liabilities	565,327	573,206
Total stockholders' equity	183,015	214,442

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

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	$ 16,549	$ 24,474
Operating expenses:		
Research and development	51,887	53,043
General and administrative	14,777	15,554
Total operating expenses	66,664	68,597
Loss from operations	(50,115)	(44,123)
Other income, net	5,159	264
Loss before income tax	(44,956)	(43,859)
Income tax expense	901	758
Net loss	$ (45,857)	$ (44,617)
Net loss per share, basic and diluted	$ (0.55)	$ (0.54)
Shares used in computing net loss per share basic and diluted	83,102,296	82,102,191

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