Alector Reports Third Quarter 2023 Financial Results and Provides Business Update

November 7, 2023

Achieved Q4 2023 target enrollment in pivotal INFRONT-3 Phase 3 latozinemab clinical trial with 103 symptomatic FTD-GRN participants

Enrollment completed in the INVOKE-2 Phase 2 clinical trial of AL002 in individuals with early Alzheimer's disease in Q3 2023, data readout expected in Q4 2024

Company to host two virtual research and development events in December highlighting TREM2 and progranulin programs

$588.9 million in cash, cash equivalents and investments provide runway through 2025

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2023 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported third quarter 2023 financial results and recent portfolio and business updates. As of September 30, 2023, Alector's cash, cash equivalents and investments totaled $588.9 million.

"We've made significant clinical advancements in our late-stage immuno-neurology programs in the second half of 2023," said   Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "Notably, we successfully completed enrollment in the INVOKE-2 Phase 2 trial in collaboration with AbbVie, positioning us for a meaningful data readout in the fourth quarter of 2024. In collaboration with GSK, we achieved our enrollment target of 103 symptomatic participants with frontotemporal dementia due to a progranulin gene mutation in the pivotal INFRONT-3 Phase 3 clinical trial of latozinemab. Further, we are progressing our strategic partnership with GSK to evaluate the potential of our progranulin programs in more prevalent neurodegenerative diseases with patient screening underway for the upcoming Phase 2 trial of AL101/GSK4257226 in early Alzheimer's disease."

Gary Romano, M.D., Ph.D., Chief Medical Officer of Alector added, "Our TREM2 and progranulin programs represent significant opportunities to harness the brain's innate immune system to treat these neurodegenerative diseases. To enhance the understanding of our novel programs, we will be hosting two events in December with renowned scientific and clinical experts who will provide greater insights into the potential of these programs."

Recent Clinical Updates

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

- In October 2023, Alector completed enrollment of 103 symptomatic and 16 at-risk participants with frontotemporal dementia due to a progranulin gene mutation (FTD-*GRN*) in the pivotal, randomized, double-blind, placebo-controlled INFRONT-3 Phase 3 clinical trial of latozinemab for a treatment duration of 96 weeks. Enrollment completion is subject to revised protocol approval in countries outside the United States.
  - Earlier this year, Alector and GSK held a Type C meeting with the U.S. Food and Drug Administration (FDA) and received scientific advice from the European Medicines Agency (EMA) regarding INFRONT-3. The companies aligned with the FDA and EMA to conduct the primary analysis on symptomatic participants, supporting an enrollment target of approximately 90-100 symptomatic participants in INFRONT-3.
- In the fourth quarter, GSK commenced patient screening in a global Phase 2 clinical trial with AL101/GSK4527226 in early Alzheimer's disease (AD). Like Latozinemab, AL101 elevates progranulin (PGRN) levels and has a different PK/PD profile.
- In September, at the 2023 Annual Meeting of the American College of Clinical Pharmacology (ACCP), Alector and GSK presented a poster on PK/PD modeling of PGRN elevation in blood and CSF based on a Phase 1 clinical trial of AL101.

TREM2 Program (AL002) Being Developed in Collaboration with AbbVie

- In September 2023, Alector completed enrollment in the randomized, double-blind, placebo-controlled, dose-ranging, INVOKE-2 Phase 2 clinical trial, with data anticipated in 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. AL002 is a novel investigational humanized monoclonal antibody that binds to TREM2 to increase TREM2 signaling and the functionality of microglia. It is the most advanced TREM2 activating product candidate in clinical development worldwide.
- Alector received payments totaling $12.5 million from AbbVie to support enrollment in the INVOKE-2 trial.

Corporate Updates

- Alector will host two virtual events in December to discuss the company's TREM2 and PGRN programs. The events will include presentations from leading scientific and clinical experts who will provide their perspectives on the biological and genetic rationale for the TREM2 and PGRN targets, share an overview of the current FTD and AD treatment landscapes, and discuss the significant unmet needs that remain in the treatment of these neurodegenerative diseases. Each event will be webcast live on the Investor section of the company's website at https://investors.alector.com.

- Details on the events are as follows:

Diving Deep into TREM2: Uncovering its Potential as a Therapeutic Target for Alzheimer's Disease

- December 7, 2023, at 9am Pacific Standard Time (PST) / 12pm Eastern Standard Time (EST)

A Detailed Review of PGRN: A Pivotal Stage Program for Frontotemporal Dementia with Broad Additional Opportunities Including Alzheimer's Disease

- December 13, 2023, at 8am PST / 11am EST

Third Quarter 2023 Financial Results

Revenue. Collaboration revenue for the quarter ended September 30, 2023, was $9.1 million, compared to $14.9 million for the same period in 2022. This decrease was primarily due to a $5.7 million decrease in collaboration revenue recognized for the AL101 programs, including a $4.6 million decrease in collaboration revenue due to an increase in total expected costs to satisfy the performance obligations for the AL101 AD program.

R&D Expenses. Total research and development expenses for the quarter ended September 30, 2023, were $46.3 million, compared to $48.3 million for the quarter ended September 30, 2022. The decrease of $2.0 million was mainly due to the Company's strategy to prioritize late-stage programs.

G&A Expenses. Total general and administrative expenses for the quarter ended September 30, 2023, were $13.4 million, compared to $14.3 million for the same period in 2022. The decrease of $0.9 million was primarily due to a decrease in consulting expenses related to accounting, recruiting, IT, and other general expenses.

Net Loss. For the quarter ended September 30, 2023, Alector reported a net loss of $44.5 million, or $0.53 per share, compared to a net loss of $46.1 million, or $0.56 net loss per share, for the same period in 2022.

Cash Position. Cash, cash equivalents, and investments were $588.9 million as of September 30, 2023. Management expects that this will be sufficient to fund current operations through 2025.

2023 Guidance. Management is reiterating its guidance for the year ending 2023. The company continues to anticipate collaboration revenue to be between $90 and $100 million, total research and development to be between $210 million and $220 million and total general and administrative expenses to be between $60 million and $65 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, planned and ongoing preclinical studies and clinical trials and the timing of data readouts from such 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 filed on November 7, 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)

	September 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 588,861	$ 712,851
Total assets	672,395	787,648
Total current liabilities (excluding deferred revenue)	74,841	45,578
Deferred revenue (including current portion)	310,409	491,601
Total liabilities	509,840	573,206
Total stockholders' equity	162,555	214,442

Consolidated Statement of Operations Data

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(in thousands, except share and per share data)

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 9,109	$ 14,852	$ 81,872	$ 119,177
Operating expense:				
Research and development	46,328	48,348	144,392	155,925
General and administrative	13,364	14,252	41,767	45,648
Total operating expenses	59,692	62,600	186,159	201,573
Loss from operations	(50,583)	(47,748)	(104,287)	(82,396)
Other income, net	7,360	2,333	18,876	4,047
Net loss before income tax	(43,223)	(45,415)	(85,411)	(78,349)
Income tax expense	1,252	733	3,546	2,533
Net loss	$ (44,475)	$ (46,148)	$ (88,957)	$ (80,882)
Net loss per share:				
Net loss per share, basic and diluted	$ (0.53)	$ (0.56)	$ (1.07)	$ (0.98)
Shares used in computing net loss per share basic and diluted	83,927,961	82,602,842	83,513,954	82,367,936

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