UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 27, 2024

Alector, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38792**	**82-2933343**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
131 Oyster Point Blvd. Suite 600 South San Francisco, California		**94080**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (415) 231-5660

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	ALEC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2024, Alector, Inc. (the "Company") announced its financial results for the quarter ended December 31, 2023. A press release announcing these results, which is attached hereto as Exhibit 99.1, is incorporated herein by reference.

All of the information furnished in Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 27, 2024
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALECTOR, INC.

Date: February 27, 2024

By: /s/ Arnon Rosenthal

Arnon Rosenthal, Ph.D.
Co-founder and Chief Executive Officer

Exhibit 99.1

Alector Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

Data from INVOKE-2, evaluating the most advanced TREM2 candidate in clinical development for early Alzheimer's disease (AD), expected in Q4 2024; trial enrollment completed in Q3 2023

First participant in the global PROGRESS-AD Phase 2 clinical trial of AL101 in early AD dosed in Q1 2024

Latozinemab granted FDA's Breakthrough Therapy Designation for frontotemporal dementia due to a mutation in the progranulin gene (FTD-GRN)

Achieved target enrollment in pivotal INFRONT-3 latozinemab Phase 3 trial in FTD-GRN during Q4 2023

$620.0 million in cash, cash equivalents and investments after January 2024 equity offering anticipated to 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., February 27, 2024 -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported fourth quarter and full year 2023 financial results and recent portfolio and business updates. As of December 31, 2023, Alector's cash, cash equivalents and investments totaled $548.9 million. Pro forma for Alector's January 2024 equity offering, cash, cash equivalents and investments total $620.0 million, which the company anticipates will provide runway through 2026.

"2023 was marked by continued progress on the execution of our late-stage clinical programs, highlighted by achieving target enrollment in both the INVOKE-2 Phase 2 trial of AL002 and the pivotal INFRONT-3 Phase 3 trial of latozinemab. Additionally, the FDA granted Breakthrough Therapy Designation to latozinemab for FTD-*GRN*, and we look forward to continued productive engagements with the FDA, recognizing the unmet need for people living with the condition. We are also pleased to report that the first patient has been dosed in the PROGRESS-AD Phase 2 trial of AL101/GSK4527226," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "Alector continues to be a pioneer in the field of immuno-neurology, and we are beginning the year with an advanced pipeline and an extended cash runway through 2026, approximately a full year beyond the expected FTD-*GRN* pivotal Phase 3 INFRONT-3 data readout. Our unwavering commitment to addressing neurodegeneration fuels progress across our clinical-stage programs,

with an anticipated data readout from the INVOKE-2 Phase 2 trial of AL002 in the fourth quarter of this year."

Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development at Alector added, "We also made meaningful strides in our Alector Brain Carrier platform, which is our proprietary blood brain barrier technology. We intend to leverage this platform technology selectively across our portfolio to increase exposure to the central nervous system by enhancing transport across the blood brain barrier. Moreover, we remain committed to the development of our early programs with additional targets in Alzheimer's disease, amyotrophic lateral sclerosis, and Parkinson's disease, which could position us to further expand our portfolio of transformative investigational therapies and achieve our ambitious vision of making brain disorders history."

Cash Runway Extension Through 2026

With $620.0 million in cash, cash equivalents and investments pro forma for the January 2024 equity offering, Alector has extended its cash runway through 2026, approximately a full year beyond the expected data readout for the pivotal Phase 3 INFRONT-3 clinical trial of latozinemab in participants with frontotemporal dementia due to a mutation in the progranulin gene (FTD-*GRN*). The extended cash runway also allows the company to selectively accelerate investment in its novel, first-in-class proprietary portfolio.

Recent Clinical Updates

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

- In February 2024, GSK dosed the first participant in the PROGRESS-AD global Phase 2 clinical trial of AL101/GSK4527226 in early Alzheimer's disease (AD), including mild cognitive impairment and mild dementia due to AD. AL101 is an investigational human monoclonal antibody (mAb) designed to block and downregulate the sortilin receptor to elevate the level of progranulin (PGRN) in the brain in a manner that is similar to latozinemab but with different pharmacokinetic (PK) and pharmacodynamic (PD) properties. Alector and GSK are co-developing AL101 for the potential treatment of more prevalent neurodegenerative diseases, including AD and Parkinson's disease.
    - In August 2023, GSK received U.S. Food and Drug Administration (FDA) clearance of its Investigational New Drug (IND) application for AL101 in the treatment of early AD. Modest reduction in the levels of PGRN due to genetic mutations has been shown to be associated with an increased risk of developing AD. Conversely, an elevation of PGRN has been shown to be protective in animal models of AD.

- In February 2024, the FDA granted Breakthrough Therapy Designation to latozinemab for the treatment of FTD-*GRN*. The FDA's Breakthrough Therapy Designation is granted to expedite the development and review of drugs in the United States that are intended to treat a serious condition when preliminary clinical evidence indicates the drug may demonstrate substantial improvement over available therapy on clinically significant endpoint(s).[1]

- In October 2023, Alector achieved target enrollment of 103 symptomatic and 16 at-risk participants with 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. Target enrollment was supported by feedback from the FDA and European Medicines Agency.

- In November 2023, Alector published a manuscript in the *International Journal of Molecular Sciences* titled, "Targeting Progranulin as an Immuno-Neurology Therapeutic Approach." The publication discusses immuno-neurology as an emerging therapeutic strategy for dementia and neurodegeneration designed to address immune surveillance failure in the brain. Immuno-neurology is a promising alternative and potentially complementary approach to current neurodegenerative therapies that focus on removing singular types of misfolded proteins from the central nervous system.

- In February 2024, Alector published a manuscript in *Alzheimer's & Dementia®: Translational Research & Clinical Interventions (TRCI*) titled, "Phase 1 study of latozinemab in progranulin-associated frontotemporal dementia." The publication outlines Phase 1b clinical trial results, demonstrating that latozinemab was well tolerated, and a favorable PK/PD profile was observed in eight symptomatic participants with FTD-*GRN*. Additionally, multiple-dose administration of latozinemab increased plasma and cerebrospinal fluid (CSF) PGRN levels in participants with FTD-*GRN* to levels approximating those seen in healthy volunteers.

TREM2 Program (AL002) Being Developed in Collaboration with AbbVie

- In September 2023, Alector completed enrollment of 381 participants in the randomized, double-blind, placebo-controlled, dose-ranging, INVOKE-2 Phase 2 clinical trial. To date, more than 90 percent of eligible participants who completed the planned treatment period of INVOKE-2 have rolled over into the long-term extension portion of the trial. INVOKE-2 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 mAb 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. Data from the trial is anticipated in the fourth quarter of 2024.

- INVOKE-2 utilizes a common close design with up to 96 weeks of randomized treatment, and all participants remain on their assigned regimen until the last participant completes 48 weeks of treatment. This design provides the opportunity to capture more observations for the primary analysis. The primary endpoint is disease progression as measured by the Clinical Dementia Rating Sum of Boxes (CDR®-SB). The CDR®-SB, which is used to assess (score) the severity of AD, is a validated instrument that assesses both cognitive and functional domains and is the FDA-accepted efficacy endpoint. The trial also employs multiple other clinical and functional outcome assessments, including CSF and plasma biomarkers, brain magnetic resonance imaging (MRI) and amyloid beta and tau positron emission tomography (PET) imaging to assess treatment effects on microglial signaling and Alzheimer's pathophysiology.

- In July 2023, Alector presented an update on INVOKE-2 at the Alzheimer's Association International Conference (AAIC). The presentation highlighted that treatment-emergent MRI findings resembling amyloid-related imaging abnormalities (ARIA) in INVOKE-2 are similar to the ARIA reported following treatment with anti-amyloid beta antibodies.
  - Alector previously presented results from a Phase 1 trial of AL002 in healthy volunteers, which demonstrated both dose-dependent target engagement and activation of microglia. In the trial, AL002 was also shown to be well tolerated.
  - Microglial activation is hypothesized to not only enhance clearance of misfolded proteins that accumulate and form amyloid plaques but also perform other supportive microglia functions, including maintenance of neuronal and synaptic health.

- Alector received a $17.8 million milestone payment from AbbVie in March 2023 after enrolling and dosing the first participants in a long-term extension (LTE) of the INVOKE-2 Phase 2 clinical trial in participants with early AD. Additionally, in 2023, Alector received payments totaling $12.5 million from AbbVie to support enrollment in the INVOKE-2 trial.

Early Research Pipeline

- Alector continues to develop its Alector Brain Carrier (ABC), a proprietary, versatile blood-brain barrier technology, which is being applied to selectively enhance its next-generation product candidates.

- The company is strategically advancing its innovative research portfolio, including the development of ADP027-ABC. The ADP027-ABC program incorporates ABC technology to enhance brain penetrance and targets modulation of the glycoprotein GPNMB for the treatment of Parkinson's disease.

Corporate

- In December 2023, Alector hosted two virtual research and development events discussing the company's TREM2 and PGRN programs in detail. The events included presentations from leading scientific and clinical experts who provided their perspectives on the biological and genetic rationale for the TREM2 and PGRN targets, shared an overview of the current FTD and AD treatment landscapes, and discussed the significant unmet need that remains in the treatment of these neurodegenerative diseases.

- In the second quarter of 2023, the U.S. Patent and Trademark Office issued a patent covering methods of treatment using AL002. The European Patent Office also issued a patent in the second quarter of 2023 covering AL002 compositions and methods of use.

Fourth Quarter 2023 Financial Results

Revenue. Collaboration revenue for the quarter ended December 31, 2023, was $15.2 million, compared to $14.4 million for the same period in 2022. Collaboration revenue for the year ended December 31, 2023, was $97.1 million, compared to $133.6 million for the same period in 2022. The decrease in year-over-year collaborative revenue was primarily due to revenue recognized from the termination of the AL003 program in 2022, offset by higher revenue recognized for the AL101 programs, including a non-cash revenue adjustment due to contract modification to have GSK operationalize the AL101 Phase 2 study and higher revenue recognized for the AL002 program due to the addition of AL002 LTE and patient replacement revenue in 2023.

R&D Expenses. Total research and development expenses for the quarter ended December 31, 2023, were $47.7 million, compared to $54.5 million for the quarter ended December 31, 2022. Total research and development expenses for the year ended December 31, 2023, were $192.1 million compared to $210.4 million for the same period in 2022. The decrease in year-over-year R&D expenses was mainly driven by the Company's strategy to prioritize late-stage programs.

G&A Expenses. Total general and administrative expenses for the quarter ended December 31, 2023, were $14.9 million, compared to $15.4 million for the quarter ended December 31, 2022. Total general and administrative expenses for the year ended December 31, 2023, were $56.7 million compared to $61.0 million for the year ended December 31, 2022. The decrease in year-over-year G&A expenses is primarily due to the decrease in consulting expenses related to accounting, recruiting, IT, and other general expenses, plus a decrease in insurance costs.

Net Loss. For the quarter ended December 31, 2023, Alector reported a net loss of $41.4 million, or $0.49 per share, compared to a net loss of $52.4 million, or $0.63 net loss per share, for the same period in 2022. For the year ended December 31, 2023, Alector reported a net loss of $130.4

million or $1.56 net loss per share, compared to a net loss of $133.3 million or $1.62 net loss per share, for the same period in 2022.

Cash Position. Cash, cash equivalents, and investments were $548.9 million as of December 31, 2023. In January 2024, Alector further strengthened its balance sheet with the completion of a follow-on financing issuing 10,869,566 shares of its common stock for total gross proceeds of $75 million before deducting underwriting discounts and commissions and estimated offering expenses. Management expects that this will be sufficient to fund current operations through 2026.

2024 Guidance. Management anticipates, for the year ending 2024, collaboration revenue to be between $60 million and $70 million, total research and development expenses to be between $210 million and $230 million, and total general and administrative expenses to be between $60 million and $70 million.

Fourth Quarter and Full Year 2023 Conference Call

Alector's management team will host a conference call discussing Alector's results for the fourth quarter and full year 2023 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: Tuesday, February 27, 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, planned and ongoing preclinical studies and 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 Annual Report on Form 10-K for 2023, filed 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)

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 548,861[1]	$ 712,851
Total assets	621,827	787,648
Total current liabilities (excluding deferred revenue)	94,973	45,578
Deferred revenue (including current portion)	293,820	491,601
Total liabilities	487,669	573,206
Total stockholders' equity	134,158	214,442

1. Pro forma for Alector's January 2024 equity offering, cash, cash equivalents and investments total $620.0 million.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 15,190	$ 14,440	$ 97,062	$ 133,617
Operating expenses:				
Research and development	47,723	54,493	192,115	210,418
General and administrative	14,920	15,385	56,687	61,033
Total operating expenses	62,643	69,878	248,802	271,451
Loss from operations	(47,453)	(55,438)	(151.740)	(137,834)
Other income, net	7,685	3,731	26,561	7,778
Net loss before income tax	(39,768)	(51,707)	(125,179)	(130,056)
Income tax expense	1,666	721	5,212	3,254
Net loss	$ (41,434)	$ (52,428)	$ (130,391)	$ (133,310)
Net loss per share, basic and diluted	$ (0.49)	$ (0.63)	$ (1.56)	$ (1.62)
Shares used in computing net loss per share basic and diluted	84,384,151	82,763,688	83,733,730	82,467,587

REFERENCES

1. U.S. Food and Drug Administration (FDA). Breakthrough Therapy.

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