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 28, 2023

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 28, 2023, Alector, Inc. (the "Company") announced its financial results for the quarter ended December 31, 2022. 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 28, 2023
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 28, 2023

By: /s/ Arnon Rosenthal

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

Exhibit 99.1

Alector Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

On track to complete 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

Preparing to engage with regulatory authorities in mid-2023 and targeting data readout from the pivotal INFRONT-3 clinical trial for latozinemab in early 2025 pending regulatory feedback

Additional data from the INFRONT-2 Phase 2 clinical trial of latozinemab in FTD-C9orf72 expected during the second half of 2023

Company and GSK plan to advance AL101 program in 2023, with the initiation of a PK bridging study to be followed by a global Phase 2 clinical trial in early Alzheimer's disease

$712.9 million in cash, cash equivalents and investments provide runway through 2025

South San Francisco, Calif., February 28, 2023 -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported fourth quarter and full year 2022 financial results and recent portfolio and business updates. As of December 31, 2022, Alector's cash, cash equivalents and investments totaled $712.9 million.

"2022 was marked by significant momentum and focus on our programs and prioritization across our pipeline as we continued to cement our position as an innovator in advancing immuno-neurology," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "We shared positive data from our INFRONT-2 Phase 2 trial of latozinemab in patients with symptomatic FTD-*C9orf72* and advanced our INVOKE-2 Phase 2 Alzheimer's disease study with AL002, the most advanced TREM2 candidate in clinical development. We are encouraged by recent progress in the Alzheimer's disease space and believe our first-in-class drug candidates that harness the power of microglia, the brain's immune cells, have the potential to improve neurodegeneration outcomes 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, "Last year was transformational for Alector as we continued to strengthen our world-class and seasoned leadership team and bolster key talent across the organization. Looking ahead, we believe we are well-positioned both financially and organizationally to execute on our strategic priorities in 2023 and beyond."

Pipeline Prioritization and Cash Runway Extension Through 2025

Alector plans to prioritize its late-stage immuno-neurology programs, including its progranulin and TREM2 product candidates, to extend cash runway through 2025.

Recent Clinical Updates and 2023 Milestones

Immuno-Neurology Portfolio
Progranulin Programs (Latozinemab, AL101) Being Developed in Collaboration with GSK

- Enrollment is ongoing globally in the INFRONT-3 randomized, placebo-controlled, pivotal Phase 3 clinical trial evaluating the efficacy and safety of latozinemab (AL001) in at-risk and symptomatic patients with frontotemporal dementia due to a progranulin gene mutation (FTD-*GRN*). In June 2022, the first patient from the trial was enrolled and dosed in the optional open-label extension (OLE) study, and enrollment in the OLE is ongoing. Alector is preparing to engage with regulatory authorities in mid-2023. The purpose of the meeting is to discuss statistical analysis plans based on emerging knowledge in the field that may enable Alector to complete the INFRONT-3 study with fewer patients and/or a shorter treatment duration. The company is targeting an INFRONT-3 data readout in early 2025 pending regulatory feedback.
- In November 2022 at the 15th Clinical Trials on Alzheimer's Disease (CTAD) conference, Alector presented positive data from the multiple-dose cohorts of the first-in-human Phase 1 study of AL101 in healthy volunteers.
    - Results demonstrated that AL101 was well tolerated and increased progranulin levels in plasma and CSF in a dose-dependent manner.
    - The pharmacokinetic (PK) and pharmacodynamic (PD) profile of AL101 supports future development in larger indications such as Alzheimer’s disease (AD) and Parkinson’s disease (PD).
    - Alector and GSK plan to advance the AL101 program in 2023, with the initiation of an Asian PK bridging study to be followed by a global Phase 2 clinical trial in early AD.
- In March 2022 at the AD/PD™ 2022 International Conference on Alzheimer’s and Parkinson’s Diseases and related neurological disorders, Alector presented positive 12-month data from the INFRONT-2 Phase 2 clinical trial of latozinemab in FTD patients with a *C9orf72* genetic mutation (FTD-*C9orf72*). These data build upon the previously disclosed study results in FTD-*GRN* patients and support the company’s efforts to expand the progranulin franchise into additional neurodegenerative disease indications.
    - Clinical outcome assessments using the CDR® plus NACC FTLD-SB scale found that treatment of FTD-*C9orf72* patients with latozinemab resulted in a trend toward a delay of approximately 54% in annualized disease progression compared to a matched control cohort from the ALLFTD consortium.

- Mean levels of glial fibrillary acidic protein (GFAP), a biomarker of astrogliosis that is an indicator of disease and/or injury to the central nervous system, decreased over 12 months in both plasma and cerebrospinal fluid (CSF) in latozinemab-treated FTD-*C9orf72* patients.
- Latozinemab was generally well tolerated when administered monthly for a year or more, consistent with other study cohorts.
- The company expects to report additional data from the INFRONT-2 trial of latozinemab in FTD-*C9orf72* patients during the second half of 2023.

TREM2 Program (AL002) Being Developed in Collaboration with AbbVie

- In January 2023, the first patient was enrolled and dosed in a long-term extension (LTE) of the INVOKE-2 Phase 2 clinical trial for which Alector will receive a $17.8 million milestone payment from AbbVie. Alector plans to complete INVOKE-2 trial enrollment 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.
- AL002 targets Triggering Receptor Expressed on Myeloid cells 2 (TREM2) to increase TREM2 signaling and the functionality of microglia.

MS4A Program (AL044)

- In September 2022, Alector commenced its first-in-human Phase 1 trial of AL044, with the intention of developing that candidate in Alzheimer's disease and potential orphan indications. Based on initial PK and tolerability data, the company decided to close the trial. Alector is actively pursuing a back-up *MS4A* program to develop an IND-ready candidate with a potentially improved dosing and tolerability profile.

Recent Corporate Updates

- In 2022, Alector expanded its management team with the appointments of Marc Grasso, M.D., as Chief Financial Officer in February, Gary Romano, M.D., Ph.D., as Chief Medical Officer in May and Peter Heutink, Ph.D., as Chief Scientific Officer in October.
- Last year the U.S. Patent and Trademark Office issued patents covering the latozinemab composition of matter and the use of AL101 for treating AD, PD and other neurodegenerative diseases including FTD.

Fourth Quarter and Full Year 2022 Financial Results

Revenue. Collaboration revenue for the quarter ended December 31, 2022, was $14.4 million, compared to $14.0 million for the same period in 2021. Collaboration revenue for the year ended December 31, 2022, was $133.6 million, compared to $207.1 million for the same period in 2021. The decrease in year-over-year collaborative revenue was primarily due to $173.4 million collaboration revenue recognized from AL001 FTD-*GRN* license provided as part of the GSK Agreement in 2021, offset by revenue recognized in 2022 for GSK and AbbVie programs, including revenue recognized from the termination of the AL003 program.

R&D Expenses. Total research and development expenses for the quarter ended December 31, 2022, were $54.5 million, compared to $52.8 million for the same period in 2021. Total research and development expenses for the year ended December 31, 2022, were $210.4 million compared to $189.4 million for the same period in 2021. The increase in R&D expenses was mainly driven by increased spending to support advancement of several clinical and preclinical programs, including latozinemab and AL002, as well as increased personnel-related expenses.

G&A Expenses. Total general and administrative expenses for the quarter ended December 31, 2022, were $15.4 million, compared to $16.9 million for the same period in 2021. Total general and administrative expenses for the year ended December 31, 2022, were $61.0 million compared to $55.0 million for the same period in 2021. The increase in year-over-year G&A expenses is primarily due to personnel-related expenses and information technology expenses to support the company's growth.

Net Loss. For the quarter ended December 31, 2022, Alector reported net loss of $52.4 million, or $0.63 net loss per share, compared to a net loss of $55.6 million, or $0.68 per share, for the same period in 2021. For the year ended December 31, 2022, Alector reported net loss of $133.3 million or $1.62 net loss per share, compared to a net loss of $36.3 million, or $0.45 net loss per share, for the same period in 2021.

Cash Position. Cash, cash equivalents, and investments were $712.9 million as of December 31, 2022. Management anticipates that this will be sufficient to fund Alector's 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, 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 2022, 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, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 712,851	$ 735,251
Total assets	787,648	814,658
Total current liabilities (excluding deferred revenue)	45,578	48,752
Deferred revenue (including current portion)	491,601	425,218
Total liabilities	573,206	513,934
Total stockholders' equity	214,442	300,724

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ 14,440	$ 13,994	$ 133,617	$ 207,085
Operating expenses:				
Research and development	54,493	52,790	210,418	189,407
General and administrative	15,385	16,933	61,033	55,038
Total operating expenses	69,878	69,723	271,451	244,445
Loss from operations	(55,438)	(55,729)	(137,834)	(37,360)
Other income, net	3,731	121	7,778	1,031
Net loss before income tax	(51,707)	(55,608)	(130,056)	(36,329)
Income tax expense	721	—	3,254	—
Net loss	$ (52,428)	$ (55,608)	$ (133,310)	$ (36,329)
Net loss per share, basic and diluted	$ (0.63)	$ (0.68)	$ (1.62)	$ (0.45)
Shares used in computing net loss per share basic and diluted	82,763,688	81,510,894	82,467,587	80,416,936

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