

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): August 03, 2023

Alector, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38792
(Commission File Number)

82-2933343
(IRS Employer
Identification No.)

131 Oyster Point Blvd.
Suite 600
South San Francisco, California
(Address of Principal Executive Offices)

94080
(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 August 3, 2023, Alector, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 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 August 3, 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: August 3, 2023

By: /s/ Arnon Rosenthal

Arnon Rosenthal, Ph.D.

Co-founder and Chief Executive Officer

Alector Reports Second Quarter 2023 Financial Results and Provides Business Update

Closed screening in the INVOKE-2 Phase 2 trial of AL002 in participants with early Alzheimer's disease; completing enrollment in Q3 2023, with data readout expected in Q4 2024

Presented update on INVOKE-2 at the Alzheimer's Association International Conference (AAIC)

Anticipate completing enrollment in pivotal INFRONT-3 trial of latozinemab with symptomatic FTD-GRN participants in Q4 2023 based on recent interactions with the FDA and EMA

\$630.0 million in cash, cash equivalents and investments provide runway through 2025; revenue and expense guidance updated for 2023

Management to host conference call and webcast today at 4:30 p.m. ET / 1:30 p.m. PT

South San Francisco, Calif., August 3, 2023 -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immunoneurology, today reported second quarter 2023 financial results and recent portfolio and business updates. As of June 30, 2023, Alector's cash, cash equivalents and investments totaled \$630.0 million.

"We expect to complete enrollment in the INVOKE-2 Phase 2 clinical trial of AL002 in early Alzheimer's disease in the third quarter," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "We have received positive feedback from the FDA and the EMA to conduct a primary analysis on approximately 90-100 symptomatic participants in our pivotal INFRONT-3 Phase 3 clinical trial of latozinemab in FTD-GRN. We anticipate completing enrollment in INFRONT-3 in the fourth quarter of this year."

Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development at Alector added, "While we continue to progress our late-stage clinical programs, we are also strategically advancing our innovative research portfolio to fuel our pipeline. I am particularly excited about the ongoing development of our blood brain barrier technology and the progress on our preclinical program targeting *GPNMB* for the treatment of Parkinson's disease."

Recent Clinical Updates***Immuno-Neurology Portfolio******TREM2 Program (AL002) Being Developed in Collaboration with AbbVie***

- Alector closed screening and plans to complete enrollment in the INVOKE-2 clinical trial in the third quarter of 2023, with data expected in the fourth quarter of 2024. The INVOKE-2 Phase 2 trial is designed to evaluate the efficacy and safety of AL002 in slowing disease progression in individuals with early Alzheimer's disease (AD).
-

- Alector presented an update on INVOKE-2 at the Alzheimer’s Association International Conference (AAIC) in July 2023. 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.
 - o 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.
 - o 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.
- At AAIC, the company also presented a poster on mouse model data demonstrating that TREM2 activation improved AD biomarkers, including amyloid and tau.

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

- 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 the pivotal INFRONT-3 Phase 3 clinical trial of latozinemab in participants with frontotemporal dementia due to progranulin gene mutation (FTD-GRN).
 - o Alector and GSK aligned with the FDA and EMA to conduct the primary analysis on symptomatic participants in INFRONT-3. Based on feedback from the regulatory agencies, the companies performed a sample size re-estimation that is anticipated to support a more focused enrollment of approximately 90-100 symptomatic participants for a treatment duration of 96 weeks.
 - o Alector plans to complete enrollment in INFRONT-3 in the fourth quarter of 2023.
 - In a recent data cut from the FTD-C9orf72 cohort of the open label INFRONT-2 Phase 2 clinical trial of latozinemab, Alector confirmed a two- to threefold elevation in progranulin levels in CSF and plasma. The company conducted an analysis of disease progression rates for the 14 participants who were treated with latozinemab compared with baseline-matched controls from the ALLFTD registry. The small sample size and a high degree of variability in disease progression in both groups rendered the results uninformative regarding treatment effect.
 - In June 2023, Alector published a manuscript in the *Journal of Translational Medicine* titled “Latozinemab, a novel progranulin-elevating therapy for frontotemporal dementia.” This publication details Alector’s development of latozinemab and highlights findings demonstrating that the sortilin receptor is a viable target for PGRN-elevating therapy, particularly in patients who have a PGRN deficiency leading to FTD.
-

- Alector and GSK plan to initiate a global Phase 2 clinical trial with AL101/GSK4527226 in early AD. The companies also plan to present a poster on the pharmacokinetic and pharmacodynamic modeling of PGRN elevation in blood and CSF based on a Phase 1 trial of AL101 at the American College of Clinical Pharmacology (ACCP) being held in Bellevue, Washington from September 10-12, 2023.

Early Research Pipeline

- Alector is developing its proprietary, versatile blood brain barrier technology to selectively support its next-generation product candidates.
- The company is developing an investigational therapy, ADP027, which modulates *GPNMB* for the treatment of Parkinson's disease.

Recent Corporate Updates

- In the second quarter of 2023, the U.S. Patent and Trademark Office issued patents 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.

Second Quarter 2023 Financial Results

Revenue. Collaboration revenue for the quarter ended June 30, 2023, was \$56.2 million, compared to \$79.9 million for the same period in 2022. The \$23.6 million decrease was mainly due to \$68.9 million of collaboration revenue recognized in the second quarter of 2022 due to changes in estimated costs to satisfy the performance obligations resulting from the termination of the AL003 program and a \$16.7 million decrease in revenue recognized for the latozinemab programs. This was offset by a \$33.5 million increase in revenue recognized for the AL101 programs, including a cumulative non-cash revenue adjustment due to contract modification to have GSK operationalize the AL101 Phase 2 trial, and a \$28.5 million increase to collaboration revenue for the AL002 program due to changes in total expected costs and the addition of AL002 LTE and patient replacement revenue in 2023.

R&D Expenses. Total research and development expenses for the quarter ended June 30, 2023, were \$46.2 million, compared to \$54.5 million for the quarter ended June 30, 2022. The decrease of \$8.4 million was mainly due to the Company's strategy to prioritize late-stage programs and higher cost share amounts with GSK that are recorded as contra expense.

G&A Expenses. Total general and administrative expenses for the quarter ended June 30, 2023, were \$13.6 million, compared to \$15.8 million for the same period in 2022. The decrease of \$2.2 million was primarily due to a decrease in consulting expenses related to accounting, recruiting, IT, and other general expenses.

Net Income. For the quarter ended June 30, 2023, Alector reported a net income of \$1.4 million, or \$0.02 net income per share, compared to a net income of \$9.9 million, or \$0.12 net income per share, for the same period in 2022.

Cash Position. Cash, cash equivalents, and investments were \$630.0 million as of June 30, 2023. Management continues to expect that this will be sufficient to fund current operations through 2025.

2023 Guidance. Management is revising guidance for the year ending 2023, increasing collaboration revenue to now be between \$90 million and \$100 million, decreasing total research and development expenses to now be between \$210 million and \$220 million and tightening expectations for total general and administrative expenses to now be between \$60 million and \$65 million.

Second Quarter 2023 Conference Call

Alector's management team will host a conference call discussing Alector's results for the second quarter of 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: Thursday, August 3, 2023
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 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 and the timing of enrollment in and data readouts from such 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 August 3, 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)**

	June 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	\$ 630,048	\$ 712,851
Total assets	708,737	787,648
Total current liabilities (excluding deferred revenue)	63,720	45,578
Deferred revenue (including current portion)	313,893	491,601
Total liabilities	512,431	573,206
Total stockholders' equity	196,306	214,442

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ 56,214	\$ 79,851	\$ 72,763	\$ 104,325
Operating expense:				
Research and development	46,177	54,534	98,064	107,577
General and administrative	13,626	15,842	28,403	31,396
Total operating expenses	<u>59,803</u>	<u>70,376</u>	<u>126,467</u>	<u>138,973</u>
Income (loss) from operations	(3,589)	9,475	(53,704)	(34,648)
Other income, net	<u>6,357</u>	<u>1,450</u>	<u>11,516</u>	<u>1,714</u>
Net income (loss) before income tax	2,768	10,925	(42,188)	(32,934)
Income tax expense	<u>1,393</u>	<u>1,042</u>	<u>2,294</u>	<u>1,800</u>
Net income (loss)	\$ 1,375	\$ 9,883	\$ (44,482)	\$ (34,734)
Net income (loss) per share:				
Basic net income (loss) per share	\$ <u>0.02</u>	\$ <u>0.12</u>	\$ <u>(0.53)</u>	\$ <u>(0.42)</u>
Diluted net income (loss) per share	\$ <u>0.02</u>	\$ <u>0.12</u>	\$ <u>(0.53)</u>	\$ <u>(0.42)</u>
Weighted-average shares used in calculating:				
Basic net income (loss) per share	<u>83,497,125</u>	<u>82,394,784</u>	<u>83,186,052</u>	<u>82,248,880</u>
Diluted net income (loss) per share	<u>83,566,293</u>	<u>82,588,368</u>	<u>83,186,052</u>	<u>82,248,880</u>

Alector Contacts:

Alector
Katie Hogan
202-549-0557
katie.hogan@alector.com

1AB (media)
Dan Budwick
973-271-6085
dan@1abmedia.com

Argot Partners (investors)
Laura Perry
212.600.1902
alector@argotpartners.com
