

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): November 04, 2021

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

Not applicable

(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 November 4, 2021 Alector, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2021. 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 November 4, 2021.
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: November 4, 2021

By: /s/ Arnon Rosenthal
Arnon Rosenthal, Ph.D.
Co-founder and Chief Executive Officer

Alector Reports Third Quarter 2021 Financial Results

Initiated Phase 2 Clinical Trial of AL001 for the Treatment of Amyotrophic Lateral Sclerosis

Executed a Global Collaboration with GSK to Co-development and Co-commercialize Alector's Progranulin Franchise Molecules for the Treatment of a Range of Neurodegenerative Diseases

South San Francisco, California, November 4, 2021 -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported third quarter 2021 financial results and summarized recent portfolio and business updates. As of September 30, 2021, Alector's cash, cash equivalents and investments totaled \$777.9 million.

"During the third quarter, Alector reached a significant inflection point, validating our immuno-neurology approach and advancing our lead programs as we strive to help patients with neurodegenerative diseases," said Arnon Rosenthal, Ph.D., co-founder and Chief Executive Officer of Alector. "We reported 12-month Phase 2 data for our lead therapeutic candidate, AL001, in which progranulin levels in frontotemporal dementia patients reverted to normal, and for the first time, showed encouraging early evidence of a slowing of disease progression across diverse datapoints. The signing of a collaborative agreement with GSK will further enable us to develop our progranulin franchise programs to their full potential in frontotemporal dementia, amyotrophic lateral sclerosis, Parkinson's disease and Alzheimer's disease. These achievements, alongside steady progress across our portfolio, are moving us ever closer to realizing our mission of harnessing the innate immune system to halt the destruction of neurodegenerative diseases."

Clinical Updates

Progranulin Franchise

- In September, Alector initiated a Phase 2 clinical trial of AL001 in amyotrophic lateral sclerosis (ALS) patients with a *C9orf72* genetic mutation. The six-month, randomized, double-blind, placebo-controlled, multicenter study is expected to enroll approximately 45 adult participants with *C9orf72*-associated ALS. The primary endpoint of the study is safety, tolerability, pharmacokinetics and pharmacodynamics of AL001, including plasma and cerebrospinal fluid (CSF) progranulin levels. The Phase 2 will also gather data on changes to multiple liquid biomarkers. ALS is the first of several indications beyond frontotemporal dementia where elevating progranulin levels is thought to have potential neuroprotective benefits.

 - AL001 received orphan drug designation from the European Commission for the treatment of frontotemporal dementia. Orphan drug designation in the EU may be granted for medicines in development for debilitating or life-threatening conditions that affect fewer than five in 10,000 people in the EU and provides benefits to the sponsor such as protocol assistance, reduced regulatory fees and extended market exclusivity. AL001 has previously received Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration.
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- Twelve-month data from the open-label INFRONT-2 Phase 2 clinical trial of AL001 in patients with frontotemporal dementia with a progranulin mutation (FTD-GRN) were presented at the Alzheimer's Association International Conference (AAIC) held in July 2021. AL001 showed a favorable safety profile, successful elevation of progranulin levels and encouraging evidence that treatment may slow disease progression.⁽¹⁾

- In July, Alector and GlaxoSmithKline (GSK) entered into a global collaboration to co-develop and co-commercialize AL001 and AL101 for the treatment of neurodegenerative diseases, including FTD-GRN, as well as other forms of FTD, ALS, Alzheimer's disease and Parkinson's disease. Under the terms of the agreement, Alector will receive \$700 million in upfront payments, \$500 million of which was received in August 2021 with a second payment to occur in the first quarter of 2022.

Alzheimer's Disease Portfolio

- Two posters were presented at the 2021 AAIC for Alector's AL002 program providing data from a Phase 1 study in healthy volunteers and details on the design of the ongoing INVOKE-2 Phase 2 clinical trial. AL002 is Alector's first-in-class monoclonal antibody that binds to the TREM2 receptor to optimize microglial activity in the brain. Alector is developing AL002 as a potential treatment for Alzheimer's disease in collaboration with AbbVie.

Corporate News

- Sam Jackson, M.D., MBA, and Linda Rubinstein joined Alector's executive leadership team assuming the roles of interim Chief Medical Officer and interim Chief Financial Officer, respectively.
 - Dr. Jackson joined Alector in 2020 as Senior Vice President, Clinical Sciences overseeing Alector's clinical science and clinical operations functions.
 - Ms. Rubinstein brings significant industry and financial experience to Alector, having served as Chief Financial Officer or interim Chief Financial Officer to numerous biotechnology companies.
- Elizabeth Garofalo, M.D., a veteran biopharmaceutical executive with more than 25 years of experience in global clinical development and regulatory affairs with a focus on neurology, was appointed to Alector's Board of Directors.

Third Quarter 2021 Financial Results

Revenue. Collaboration revenue for the quarter ended September 30, 2021, was \$182.4 million, compared to \$5.9 million for the same period in 2020. In August, Alector received \$500 million as part of the collaboration agreement with GSK. The increase in 2021 third quarter revenue was mainly due to the recognition of \$179.8 million of the upfront payment from GSK.

R&D Expenses. Total research and development expenses for the quarter ended September 30, 2021, were \$43.1 million, compared to \$43.8 million for the quarter ended September 30, 2020. The decrease in R&D expenses was attributable to timing of manufacturing of drug supply and clinical trials start-up costs.

G&A Expenses. Total general and administrative expenses for the quarter ended September 30, 2021, were \$13.0 million, compared to \$15.8 million for the same period in 2020. This decrease was primarily due to reduced legal fees.

Net Income (Loss). For the quarter ended September 30, 2021, Alector reported a net income of \$126.6 million, or \$1.56 net income per share, compared to a net loss of \$52.7 million, or \$0.67 net loss per share, for the same period in 2020.

Cash Position. Cash, cash equivalents, and marketable securities were \$777.9 million as of September 30, 2021.

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 the 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. This scientific approach is also the basis for the company's immuno-oncology programs. Alector is headquartered in South San Francisco, California. For additional information, please visit www.alector.com.

⁽¹⁾ Paul, Robert, et al, "AAIC 2021 "Twelve month Results from the INFRONT-2 Phase 2 Open-label Clinical Study of AL001 in Frontotemporal Dementia Patients with a Progranulin Mutation (FTD-GRN)"

⁽²⁾ Guerreiro, et al. "TREM2 Variants in Alzheimer's Disease" NEJM. 2013; and Jonsson, et al. "Variant of TREM2 associated with the risk of Alzheimer's disease" NEJM 2013

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to risks and uncertainties related to market conditions, Alector and its business as set forth in our Quarterly Report on Form 10-Q, as filed on November 4, 2021 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, 2021	December 31, 2021
Cash, cash equivalents, and marketable securities	\$ 777,850	\$ 413,308
Total assets	854,226	488,251
Total current liabilities (excluding deferred revenue)	38,132	44,202
Deferred revenue (including current portion)	439,212	132,303
Total liabilities	518,336	220,721
Total stockholders' equity	336,409	267,530

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	\$ 182,413	\$ 5,904	\$ 193,091	\$ 16,245
Operating expense:				
Research and development	43,066	43,819	136,617	112,486
General and administrative	13,018	15,834	38,105	46,175
Total operating expenses	56,084	59,653	174,722	158,661
Income (loss) from operations	126,329	(53,749)	18,369	(142,416)
Other income, net	268	1,045	910	4,367
Net income (loss)	\$ 126,597	\$ (52,704)	\$ 19,279	\$ (138,049)
Net income(loss) per share:				
Basic net income(loss) per share	\$ 1.56	\$ (0.67)	\$ 0.24	\$ (1.78)
Diluted net income(loss) per share	\$ 1.49	\$ (0.67)	\$ 0.23	\$ (1.78)
Weighted-average shares used in calculating:				
Basic net income(loss) per share	80,964,701	78,771,930	80,048,758	77,340,896
Diluted net income(loss) per share	85,232,690	78,771,930	82,871,254	77,340,896

Alector Contacts

Michelle Corral
VP, Communications and Investor Relations
650-808-7016
michelle.corral@alector.com

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

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