

# Alector Reports Second Quarter 2023 Financial Results and Provides Business Update

August 3, 2023

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., Aug. 03, 2023 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, 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.
  - 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.
  - 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.
  - 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 baselinematched 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 <a href="https://www.alector.com">www.alector.com</a>.

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 <a href="https://investors.alector.com/events-and-presentations/events">https://investors.alector.com/events-and-presentations/events</a> and following the event a replay will be archived there for 30 days. Interested participating by phone will need to register using this <a href="https://investors.alector.com/events-and-presentations/events">noline form</a>. 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 <a href="https://www.alector.com">www.alector.com</a>.

## **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)

			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		59,803		70,376	_	126,467		138,973
Income (loss) from operations		(3,589)		9,475		(53,704)		(34,648)
Other income, net		6,357		1,450		11,516		1,714
Net income (loss) before income tax		2,768		10,925		(42,188)		(32,934)
Income tax expense		1,393		1,042	_	2,294		1,800
Net income (loss)	\$	1,375	\$	9,883	\$	(44,482)	\$	(34,734)
Net income (loss) per share:								
Basic net income (loss) per share	\$	0.02	\$	0.12	\$	(0.53)	\$	(0.42)
Diluted net income (loss) per share	\$	0.02	\$	0.12_	\$	(0.53)	\$	(0.42)
Weighted-average shares used in calculating:				_				
Basic net income (loss) per share		83,497,125		82,394,784		83,186,052		82,248,880
Diluted net income (loss) per share		83,566,293		82,588,368		83,186,052		82,248,880

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