Alector Reports Fourth Quarter and Full Year 2021 Financial Results

February 24, 2022

CTAD and SITC presentations in fourth quarter highlight progress across immuno-neurology and immuno-oncology portfolio

Over $900 million in pro forma cash, cash equivalents and investments supports execution of clinical, research and operational goals

Steady continued enrollment in progranulin franchise clinical trials for AL001 and AL101 and TREM2-targeting program for Alzheimer's disease, AL002

SOUTH SAN FRANCISCO, Calif., Feb. 24, 2022 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering the discovery and development of immuno-neurology therapeutics, today reported fourth quarter and full year 2021 financial results and summarized recent portfolio and business updates. As of December 31, 2021, Alector's cash, cash equivalents and investments totaled $735.3 million. In addition, the company received a $200 million payment from partner GlaxoSmithKline (GSK) in January 2022.

"Over the past year, we made important strides in advancing our clinical and preclinical pipeline of candidates harnessing the innate immune system to address genetically validated targets against neurodegenerative diseases," said Arnon Rosenthal, Ph.D., co-founder and Chief Executive Officer of Alector. "We shared the largest data set to date in individuals with frontotemporal dementia and established a transformative collaboration with GlaxoSmithKline designed to expand and accelerate the development of our progranulin franchise candidates, AL001 and AL101. We are building on this momentum in 2022; with three new INDs on the horizon, we expect to end the year with seven therapeutic candidates in clinical trials. With our strong balance sheet, expanded leadership team, growing development capabilities, maturing pipeline and productive research platform, we are well-positioned to execute our mission."

Recent Clinical Updates and 2022 Milestones

Progranulin Programs: AL001 and AL101
Alector is developing monoclonal antibodies AL001 and AL101 to elevate levels of progranulin in the brain in partnership with GSK. Mutations resulting in progranulin deficiencies are known to be a causal factor for frontotemporal dementia (FTD) and a risk factor for amyloid lateral sclerosis (ALS), Alzheimer's disease and Parkinson's disease. In July 2021, Alector entered into a global collaboration with GSK to co-develop and co-commercialize AL001 and AL101. Alector is actively enrolling the INFRONT-3 Phase 3 pivotal clinical study of AL001 in at-risk and symptomatic carriers of frontotemporal dementia with a progranulin mutation (FTD-*GRN*).

- In January 2022, the journal *Trends in Pharmacological Sciences* published a review article in press, "Progranulin as a therapeutic target in neurodegenerative diseases" by Alector authors as part of the journal's special issue, "Advances in neuro-immunology based therapeutic opportunities".

- In November 2021, Alector presented data from the INFRONT-2 Phase 2 open-label clinical study of AL001 in patients with symptomatic FTD-*GRN* at the 14th Clinical Trials on Alzheimer's Disease (CTAD) medical meeting.
    - AL001 restored progranulin to normal levels for the entire duration of treatment. In addition, multiple biomarkers known to be elevated in FTD-*GRN* decreased toward normal levels following treatment with AL001. Clinical outcome assessments of AL001-treated patients showed slowing of clinical progression by 48% compared to a matched control cohort of participants from the Genetic FTD Initiative (GENFI2).
    - The totality of the Phase 2 data and consistent response across diverse endpoints support the continued evaluation of AL001 in the ongoing INFRONT-3 Phase 3 study.
    - AL001 was generally well tolerated when administered monthly for a year or more.

- Twelve-month data from Alector's INFRONT-2 Phase 2 clinical trial of AL001 in a cohort of patients with FTD with a *C9orf72* genetic mutation have been accepted for presentation at the International Conference on Alzheimer's and Parkinson's Diseases (ADPD) in March 2022.

- In November 2021 Alector presented interim results from the AL101 first-in-human study of healthy volunteers. The study established that AL101 was effectively distributed into the central nervous system (CNS) and showed proof of mechanism, with increases in progranulin levels observed in the periphery and the brain persisting for one month.
    - AL101 was found to be generally well tolerated with single-dose IV or SC administration.
    - The AL101 Phase 1 study is continuing to enroll additional cohorts to test further dosages of AL101 administered intravenously or subcutaneously and is expected to be completed by the end of 2022.

Alzheimer's Disease Portfolio
AL002 and AL003 are Alector's clinical-stage immuno-neurology antibodies being advanced for the treatment of Alzheimer's disease. AL002 is intended to optimize microglial activity in the brain to combat Alzheimer's disease by binding to the TREM2 receptor to stimulate microglia activity. AL003 blocks the Siglec3, or CD33, checkpoint inhibitor to increase microglia activity. Both are being developed in collaboration with AbbVie.

- In November 2021, Alector presented Phase 1 data for AL003 in healthy volunteers and participants with Alzheimer's disease at CTAD. AL003 was found to be well tolerated when administered monthly at doses up to and including 15 mg/kg. AL003 demonstrated target engagement of CD33 in both blood and CNS compartments at well tolerated doses.

- In the fourth quarter 2021, Alector reported that Amyloid Related Imaging Abnormalities (ARIA) have been observed in the ongoing AL002 INVOKE-2 Phase 2 clinical trial in Alzheimer's disease.
    - While the large majority of ARIA cases observed were asymptomatic and non-serious, a small number of serious adverse events occurred in participants carrying two identical alleles of the APOE (apolipoprotein E) gene mutation. In addition to protocol amendments voluntarily put in place last year to mitigate risks associated with ARIA, Alector plans to voluntarily amend the Phase 2 trial protocol to exclude APOE e4/e4 homozygotes and to discontinue dosing of APOE e4/e4 homozygotes currently on study. The potential impact, if any, of this protocol amendment on timing to complete enrollment of the INVOKE-2 Phase 2 clinical trial is being assessed.

Early-Stage Pipeline in Neurodegenerative Diseases and Oncology
In 2022 Alector plans to advance three novel therapeutic candidates, including the company's first immuno-oncology agents, into first-in-human clinical studies.

- A Phase 1 clinical study of treatment with AL008 in patients with advanced solid tumors is expected to begin in the first half of 2022 in China. This first-in-human study will be led by Alector's regional partner, Innovent Biologics. AL008 is a novel innate immuno-oncology candidate with a dual mechanism of action that combines inhibition of the CD47-SIRP-alpha (SIRPα) pathway with stimulation of activating Fc receptors.

- In November 2021, Alector presented preclinical data from its AL009 immuno-oncology program at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting. *In vivo,* AL009 led to dose-dependent increases in immune stimulatory molecules consistent with the repolarization of myeloid-derived suppressive cells to a proinflammatory state. A Phase 1 clinical study of AL009 in patients with advanced solid tumors is expected to begin in the second half of 2022. AL009 is a first-in-class multi SIGLEC inhibitor.

- Alector plans to initiate the first-in-human study for AL044 in the second half of 2022. AL044 targets *MS4A,* a risk gene family for Alzheimer's disease. MS4A is expressed selectively in microglia and is associated with control of microglia functionality and potential viability.

Recent Corporate News

- In January 2022, Alector received the remaining $200 million from its $700 million committed upfront payment from the GSK collaboration agreement signed by the two companies in July 2021. Under the terms of the agreement, Alector will also be eligible for up to $1.5 billion in potential development, regulatory and commercial milestone payments, as well as profit-sharing in the U.S. and royalties on any ex-U.S. sales.
- Alector expanded its management team with the appointments of Sara Kenkare-Mitra, Ph.D., as Alector's President and Head of Research and Development, and Marc Grasso, M.D., as Chief Financial Officer.
    - Dr. Kenkare-Mitra joined Alector in December 2021 from Genentech, where she served as Senior Vice President of Development Sciences. Dr. Kenkare-Mitra brings more than 23 years of experience overseeing the transition of molecules from discovery to the clinic and throughout clinical development.
    - Dr. Grasso joined Alector from Kura Oncology, where he served as Chief Financial Officer and Chief Business Officer. Prior to Kura, he spent over twenty years in investment banking advising biotechnology and pharmaceutical companies.

Fourth Quarter and Full Year 2021 Financial Results

Revenue. Collaboration revenue for the quarter ended December 31, 2021, was $14.0 million, compared to $4.9 million for the same period in 2020. Collaboration revenue for the year ended December 31, 2021, was $207.1 million compared to $21.1 million for the same period in 2020. The increase in year-over-year collaborative revenue was primarily driven by the strategic collaboration with GSK.

R&D Expenses. Total research and development expenses for the quarter ended December 31, 2021, were $52.8 million compared to $44.4 million for the quarter ended December 31, 2020. Total research and development expenses for the year ended December 31, 2021, were $189.4 million compared to $156.9 million for the same period in 2020. This change in 2021 R&D expenses was mainly driven by increased spending to support advancement of several clinical and preclinical programs, as well as increased personnel-related expenses.

G&A Expenses. Total general and administrative expenses for the quarter ended December 31, 2021, were $16.9 million compared to $13.2 million for the same period in 2020. This increase was primarily due to an increase in personnel-related expenses. Total general and administrative expenses for the year ended December 31, 2021, were $55.0 million compared to $59.4 million for the same period in 2020. This decrease was primarily due to a decrease in legal costs associated with Alector's arbitration proceedings in 2020 partially offset by an increase in personnel-related expenses.

Net Loss. For the quarter ended December 31, 2021, Alector reported a net loss of $55.6 million, or $0.68 per share, compared to a net loss of $52.2

million, or $0.66 per share, for the same period in 2020. For the year ended December 31, 2021, Alector reported a net loss of $36.3 million, or $0.45 net loss per share, compared to a net loss of $190.2 million, or $2.45 net loss per share, for the same period in 2020.

Cash Position. Cash, cash equivalents, and marketable securities were $735.3 million as of December 31, 2021. In addition, the company received a $200 million payment from partner GSK in January 2022.

Cash Guidance. Alector continues to anticipate that the company's existing cash, cash equivalents, and marketable securities, including the net proceeds received from GSK in January 2022, are sufficient to fund projected operations into mid-2024.

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.

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 preclinical studies, clinical trials, expected milestones, expectations of our collaborations, and financial and cash guidance. 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 Alector's Annual Report on Form 10-K, as filed on February 24, 2022 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, 2021	December 31, 2020
Cash, cash equivalents, and marketable securities	$ 735,251	$ 413,308
Total assets	814,658	488,251
Total current liabilities (excluding deferred revenue)	48,218	44,202
Deferred revenue (including current portion)	425,218	132,303
Total liabilities	513,934	220,721
Total stockholders' equity	300,724	267,530

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Collaboration revenue	$ 13,994	$ 4,853	$ 207,085	$ 21,098
Operating expenses:				
Research and development	52,790	44,383	189,407	156,869
General and administrative	16,933	13,228	55,038	59,403
Total operating expenses	69,723	57,611	244,445	216,272
Loss from operations	(55,729)	(52,758)	(37,360)	(195,174)
Other income, net	121	579	1,031	4,946
Net loss	$ (55,608)	$ (52,179)	$ (36,329)	$ (190,228)
Net loss per share, basic and diluted	$ (0.68)	$ (0.66)	$ (0.45)	$ (2.45)
Shares used in computing net loss per share basic and diluted	81,510,894	78,998,656	80,416,936	77,758,806

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