Alector Reports Second Quarter 2022 Financial Results and Provides Business Update

August 4, 2022

Investigational New Drug Application submitted for AL044, a novel drug candidate targeting an Alzheimer's disease risk gene

Expanding clinical sites to drive additional enrollment in the INFRONT-3 pivotal study for latozinemab (AL001) and enrollment continues in the INVOKE-2 Phase 2 study for AL002

Peter Heutink, Ph.D., to join company as Chief Scientific Officer

John Maraganore appointed as strategic advisor

$808.9 million in cash, cash equivalents and investments provide runway into H2-2024

SOUTH SAN FRANCISCO, Calif., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today reported second quarter 2022 financial results and recent portfolio and business updates. As of June 30, 2022, Alector's cash, cash equivalents and investments totaled $808.9 million.

Commentary on the Quarter:

"We continue to make significant progress in building our pipeline of novel immuno-neurology and immuno-oncology drug candidates which engage the innate immune system to treat neurodegeneration and cancer," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector.

"With the recent submission of an Investigational New Drug Application (IND) for our next first-in-class clinical drug candidate, AL044, Alector continues to build its position as an innovator in developing new approaches to tackle Alzheimer's disease (AD) and other serious neurodegenerative disorders. The company is planning its first AL044 study in healthy volunteers. AL044 modulates MS4A, which is a genetic risk locus for AD and an immune checkpoint expressed on microglia cells. MS4A activity is associated with multiple AD pathologies, including: Abeta and Tau accumulation, earlier age of onset, and increased rate of cognitive decline. We believe that AL044 has significant potential to be effective in the treatment of AD."

"Patient enrollment is progressing in INVOKE-2, a Phase 2 study of AL002, which is our first-in-class anti-TREM2 antibody for early AD. Following a voluntary exclusion of APOE e4/e4 homozygous patients, we have not observed additional serious adverse events related to amyloid-related imaging abnormalities (ARIA). We are implementing earlier patient monitoring to the trial that is consistent with recently published guidelines for ARIA monitoring and management as we continue to prioritize patient safety. TREM2 is an important risk gene for AD and is believed to control the survival, function, proliferation, and migration of microglia, the brain's immune cells."

"In addition to our robust AD portfolio, we are opening additional sites and expanding recruitment efforts to enroll our Phase 3 INFRONT-3 pivotal study of latozinemab for frontotemporal dementia (FTD) with progranulin mutations (FTD-*GRN*). Later this year, we also expect to share new data from the Phase 1 study of AL101, the second product candidate from the company's progranulin portfolio."

Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development at Alector, added, "We are pleased to announce that the company has completed IND enabling studies for our immuno-oncology program, AL009, and anticipates submitting an IND in 2022. AL009 is a first-in-class multi Siglec inhibitor that works to enhance both the innate and adaptive immune system response to tumors by blocking a critical glycan checkpoint pathway that drives immune inhibition. As a leader in targeting myeloid biology, this brings us closer to achieving our goal of building a portfolio of innate immuno-oncology therapies by utilizing the company's expertise in the central and peripheral innate immune system."

"Alongside these encouraging clinical updates, Alector continues to attract world class talent and we are delighted to announce that Peter Heutink, Ph.D., will be joining us as Chief Scientific Officer. Peter brings considerable experience in human genetics of neurodegenerative diseases, functional genomics, and induced pluripotent stem cell (iPSC) technology that will help drive science and discovery at Alector."

Clinical Programs

Immuno-Neurology Portfolio
Progranulin Assets (Latozinemab, AL101)

- Alector continues to progress the INFRONT-3 randomized, placebo-controlled, pivotal Phase 3 trial evaluating the efficacy and safety of latozinemab in at-risk and symptomatic patients with FTD-*GRN*. The company continues to build awareness of FTD, support genetic testing and educate the FTD patient community about the INFRONT-3 pivotal study to support clinical trial enrollment.

- The company expects to report data at a medical conference later this year from the Phase 1 trial of AL101 in healthy volunteers. AL101 is being developed to elevate progranulin levels in a manner similar to latozinemab (AL001) with plans to investigate AL101 for the treatment of AD and Parkinson's disease.

TREM2 and SIGLEC 3 Assets (AL002, AL003)

- Enrollment in the INVOKE-2 Phase 2 study of AL002 continues with no additional serious adverse events related to ARIA

following the exclusion of APOE e4/e4 homozygous patients. The company is implementing MRI monitoring prior to dose escalation for all clinical trial participants, consistent with recently published guidelines for ARIA monitoring and management. The INVOKE-2 Phase 2 clinical trial is designed to evaluate the efficacy and safety of AL002 in slowing disease progression in individuals with early AD. AL002 is being developed in collaboration with AbbVie and targets Triggering Receptor Expressed on Myeloid cells 2 (TREM2) to increase TREM2 signaling and the functionality of microglia brain specific immune cells.

- As previously announced, AbbVie decided to terminate the CD33 collaboration program after Alector and AbbVie collaboratively reviewed next steps for AL003, which targets CD33. Both companies concluded the program did not warrant further development based on insufficient evidence of an effect on pharmacodynamic biomarkers from a Phase 1 study. This decision allows Alector to focus its resources on other more promising programs.

Novel MS4A Asset (AL044)

- Alector has submitted a U.S. IND for AL044, which targets MS4A, a major genetic risk locus for AD and an immune checkpoint expressed on microglia immune system cells. Preclinical data suggest that AL044 may mimic or surpass the effects of a genetic variant of MS4A that is protective against AD.

Immuno-Oncology Portfolio
SIRPα and Multi-Siglec Assets (AL008, AL009)

- The company intends to re-acquire the rights that were granted to Innovent Biologics for the development and commercialization of AL008. Innovent submitted an IND to the Chinese regulatory authorities, and Alector plans to utilize data and documentation from this regulatory filing to support a potential IND submission in the U.S. AL008 is a novel innate immuno-oncology candidate with a dual mechanism of action combining the inhibition of the CD47-SIRP-alpha (SIRPα) pathway with the activation of Fc receptors to promote immuno-stimulatory pathways that drive anti-tumor immunity.

- The company has completed IND enabling studies for its first-in-class AL009 immuno-oncology program and anticipates submitting an IND later this year. AL009 is a dual function biologic that inhibits multiple Siglec receptors on myeloid cells and simultaneously activates a stimulating receptor on the same cells. The company plans to prioritize tumor types that have immunosuppressive phenotypes and expects to study AL009 as a monotherapy and in combination with standard of care.

Recent Corporate Updates

- Dr. Peter Heutink, Ph.D., will join Alector as its soon-to-be new Chief Scientific Officer (CSO) in the fall of 2022. Dr. Heutink is a full professor, a group leader and the site speaker of the German Center for Neurodegenerative Diseases (DZNE) – Tübingen. In addition, he is a full professor of Genome Biology for Neurodegenerative Diseases at the Eberhard Karls University Tübingen, Germany and an honorary professor of Functional Genomics of Ageing and Neurodegeneration at the University Medical Center Groningen (UMCG), the Netherlands. Dr. Heutink has led teams that identified mutation in genes for Parkinson's disease, FTD, chorea, ataxia, hemochromatosis, porencephaly and various development disorders. He has also made important contributions to genome wide association studies for major depression, Tourette Syndrome, obsessive compulsive disorders, FTD, and Parkinson's Disease. He has made contributions to a series of genome wide association, exome and whole genome sequencing studies as a member of the International Parkinson's Disease Genomics Consortium (IPDGC), the International Frontotemporal Dementia Genomics Consortium (IFGC) and the International FTLD-TDP WGS consortium and is a member of the steering committee of the Global Parkinson's Genetics Program. Dr. Heutink has been involved in many industry collaborations to bring genetic findings towards the clinic and is an author/co-author of over 400 peer-reviewed publications.

- John Maraganore has joined Alector as a strategic advisor. Mr. Maraganore served as the founding CEO and Director at Alnylam Pharmaceuticals where he led the company's efforts to form significant partnerships with leading pharmaceutical and biotech companies and built an integrated biotech company with a market capitalization exceeding $25 billion.

- The U.S. Patent and Trademark Office has issued additional patents covering the latozinemab composition of matter and the use of AL101 for treating AD, Parkinson's disease and other neurodegenerative diseases including FTD.

Second Quarter 2022 Financial Results

Revenue. Collaboration revenue for the quarter ended June 30, 2022, was $79.9 million, compared to $6.6 million for the same period in 2021. The increase of $73.3 million was due to a $52.0 million net increase to collaboration revenue under the AbbVie Agreement due to changes in estimated costs to satisfy the performance obligations resulting from the termination of the AL003 program, partially offset by increases in total expected costs for the AL002 program. The increase was also due to a $21.3 million increase in revenue recognized from the GSK Agreement.

R&D Expenses. Total research and development expenses for the quarter ended June 30, 2022, were $54.5 million, compared to $47.8 million for the quarter ended June 30, 2021. The increase in R&D expenses was mainly driven by increased personnel-related expenses, including stock-based compensation, as well as an increase in AL101 expenses.

G&A Expenses. Total general and administrative expenses for the quarter ended June 30, 2022, were $15.8 million, compared to $14.1 million for the same period in 2021. The increase was primarily due to an increase in personnel-related expenses, including stock-based compensation, offset by reduced legal expenses mainly to support the GSK collaboration deal in 2021.

Net Income (Loss). For the quarter ended June 30, 2022, Alector reported net income of $9.9 million, or $0.12 net income per share, compared to a net loss of $55.1 million, or $0.69 net loss per share, for the same period in 2021.

Cash Position. Cash, cash equivalents, and investments were $808.9 million as of June 30, 2022. Management anticipates that this will be sufficient to fund current operations into the second half of 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 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 risks and uncertainties, including but not limited to risks and uncertainties as set forth in Alector's Quarterly Report on Form 10-Q, as filed on August 4, 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)

	June 30, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 808,855	$ 735,251
Total assets	889,672	814,658
Total current liabilities (excluding deferred revenue)	42,415	48,752
Deferred revenue (including current portion)	520,893	425,218
Total liabilities	601,156	513,934
Total stockholders' equity	288,516	300,724

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 79,851	$ 6,568	$ 104,325	$ 10,678
Operating expense:				
Research and development	54,534	47,818	107,577	93,551
General and administrative	15,842	14,075	31,396	25,087
Total operating expenses	70,376	61,893	138,973	118,638
Income (loss) from operations	9,475	(55,325)	(34,648)	(107,960)
Other income, net	1,450	178	1,714	642
Net income (loss) before income tax	10,925	(55,147)	(32,934)	(107,318)
Income tax expense	1,042	—	1,800	—
Net income (loss)	$ 9,883	$ (55,147)	$ (34,734)	$ (107,318)
Net income (loss) per share:				

Basic net income (loss) per share	$ 0.12	$ (0.69)	$ (0.42)	$ (1.35)
Diluted net income (loss) per share	$ 0.12	$ (0.69)	$ (0.42)	$ (1.35)
Weighted-average shares used in calculating:				
Basic net income (loss) per share	82,394,784	79,790,036	82,248,880	79,598,188
Diluted net income (loss) per share	82,588,368	79,790,036	82,248,880	79,598,188

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