Alumis Reports Third Quarter 2024 Financial Results and Highlights Recent Achievements

November 13, 2024

– Presented data at EADV supporting potential of ESK-001 as differentiated oral treatment in immune-mediated diseases through maximal TYK2 inhibition –

– Continued to advance three clinical programs, including global Phase 3 ONWARD clinical trials for ESK-001 in moderate-to-severe plaque psoriasis, Phase 2b clinical trial for ESK-001 in systemic lupus erythematosus (SLE) and Phase 1 clinical study for A-005 being developed for neuroinflammatory and neurodegenerative diseases –

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Alumis Inc. (Nasdaq: ALMS), a clinical-stage biopharmaceutical company developing oral therapies using a precision approach to optimize clinical outcomes and significantly improve the lives of patients with immune-mediated diseases, today reported financial results for the third quarter ended September 30, 2024, and highlighted recent achievements and upcoming milestones.

"I am pleased with the important progress we've made across our three clinical programs, as the team continues to show operational focus and execution, leveraging this momentum towards important upcoming data readouts," said Martin Babler, President and Chief Executive Officer of Alumis. "ESK-001 and A-005 are designed to be differentiated in the TYK2 space by achieving maximal TYK2 inhibition at doses with a favorable safety profile. With the potential to combine high biologic-like efficacy with oral convenience, we are well positioned to deliver on the promise and impact that TYK2 inhibition can have for patients with immune-mediated diseases."

Babler continued, "We look forward to continuing to generate data with a goal of supporting best-in-class profiles for our programs, with A-005 Phase 1 data expected by year end and ESK-001 52-week Phase 2 OLE study data expected in the first quarter of 2025."

Third Quarter 2024 Highlights

- **Presented data at 2024 European Academy of Dermatology & Venereology (EADV) Congress supporting ESK-001's potential to offer a differentiated and best-in-class treatment profile for people with moderate-to-severe plaque psoriasis:**
    - Late-breaking 28-week data from the Open Label Extension (OLE) Phase 2 study show ESK-001 was generally well tolerated and most patients treated with the top dose of 40 mg twice daily achieved primary endpoint of PASI 75 (93% as observed (AO, n=71), 82.7% using modified non-responder imputation (mNRI, n=81)); Also, sPGA 0/1 responses of 76.1% (AO, n=71) and 67.9% (mNRI, n=81) were observed.
    - Additional data presented show that the 40 mg twice daily dose, which achieves maximal target inhibition according to blood and skin biopsy biomarkers, leads to the highest response rates. Importantly, positive efficacy and safety outcomes are associated with significant improvements in patients' reported quality of life outcomes. These findings support use of the 40 mg twice daily dose in the ongoing Phase 3 clinical program.

- **Continued to advance three clinical programs in immune-mediated diseases:**
  - The Phase 3 ONWARD program for ESK-001 in moderate-to-severe plaque psoriasis consists of two parallel 24-week global Phase 3 clinical trials (ONWARD1 and ONWARD2) designed to evaluate the efficacy and safety of ESK-001 in adult patients with moderate-to-severe plaque psoriasis and also includes a long-term extension (LTE) trial, ONWARD3, designed to evaluate durability and maintenance of response and long-term safety. Topline results are anticipated in the first half of 2026.
  - The Phase 2b LUMUS program for ESK-001 in SLE is designed to evaluate the efficacy, safety and pharmacokinetics of multiple doses of ESK-001 in adult patients with moderately to severely active, autoantibody-positive SLE. Topline results are anticipated in 2026.
  - The Phase 1 clinical study of A-005, a potential first-in-class, central nervous system (CNS) penetrant TYK2 inhibitor being developed for the treatment of neuroinflammatory and neurodegenerative diseases, is designed to assess the safety, tolerability, and pharmacokinetics of single and multiple-ascending orally administered doses of A-005 in healthy participants, including confirmation of CNS penetration in humans. Data readout is anticipated by year-end 2024.

Anticipated Milestones

2024

- **A-005:** Phase 1 clinical study data in healthy participants (by year-end)

2025

- **A-005:** Initiation of Phase 2 clinical trial in multiple sclerosis (MS)
- **ESK-001**: Phase 2 OLE 52-week data update in psoriasis
- **Third pipeline program**: Investigational New Drug Application filing for third clinical candidate

2026

- **ESK-001**: Psoriasis Phase 3 topline data (1H 2026)
- **ESK-001**: SLE Phase 2b topline data
- **A-005**: MS Phase 2 topline data

Third Quarter 2024 Financial Results

- As of September 30, 2024, Alumis had cash and cash equivalents and marketable securities of $361.9 million, which is expected to fund operations into 2026.
- Research and development expenses were $87.8 million for the quarter ended September 30, 2024, compared to $37.8 million for the same period in 2023. The increase was driven by a clinical milestone payment of $23.0 million related to a prior acquisition of FronThera, an increase in contract manufacturing and clinical trial costs for the ESK-001 and A-005 programs, as well as increased headcount in research and development teams to support development efforts.
- General and administrative expenses were $10.6 million for the quarter ended September 30, 2024, compared to $6.0 million for the same period in 2023. The increase was primarily attributable to personnel-related expenses and professional consulting services to support the Company’s growth and business development.
- Net loss was $93.1 million for the quarter ended September 30, 2024, compared to $43.4 million for the same period in 2023.

Upcoming Events

- Alumis will be presenting two posters at ACR Convergence 2024, the annual meeting of the American College of Rheumatology (ACR) taking place November 14-19 in Washington, D.C.

About Alumis

Alumis is a clinical-stage biopharmaceutical company developing oral therapies using a precision approach to optimize clinical outcomes and significantly improve the lives of patients with immune-mediated diseases. Leveraging its proprietary precision data analytics platform, Alumis is building a

pipeline of molecules with the potential to address a broad range of immune-mediated diseases as monotherapy or combination therapies. Alumis' most advanced product candidate, ESK-001, is an oral, highly selective, small molecule, allosteric inhibitor of tyrosine kinase 2 that is currently being evaluated for the treatment of patients with moderate-to-severe plaque psoriasis and systemic lupus erythematosus. Alumis is also developing A-005, a CNS-penetrant, allosteric TYK2 inhibitor for the treatment of neuroinflammatory and neurodegenerative diseases. Beyond TYK2, Alumis' proprietary precision data analytics platform and drug discovery expertise have led to the identification of additional preclinical programs that exemplify its precision approach. Incubated by Foresite Labs and led by a team of industry veterans experienced in small-molecule compound drug development for immune-mediated diseases, Alumis is pioneering a precision approach to drug development to potentially produce the next generation of treatment to address immune dysfunction. For more information, visit www.alumis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding Alumis' future plans and prospects, its anticipated milestones (including, without limitation, the expected timing of clinical trial results), its participation at upcoming conferences, its ability to accomplish its mission to bring new, effective treatment options to patients living with immune-mediated diseases, the success, cost and timing of its product candidate development activities and current and future clinical trials and studies, including study design, any expectations regarding the safety, efficacy or tolerability of ESK-001, including based on the clinical update from Alumis' Phase 2 STRIDE clinical trial and ongoing OLE study, the ability of ESK-001 to treat moderate-to-severe plaque psoriasis or SLE, any expectations regarding the safety, efficacy or tolerability of A-005, and the ability of A-005 to treat MS and other neuroinflammatory and neurodegenerative diseases, and expectations regarding the sufficiency and runway of capital resources. Any forward-looking statements in this press release are based on Alumis' current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Readers are cautioned that actual results, levels of activity, safety, efficacy, performance or events and circumstances could differ materially from those expressed or implied in Alumis' forward-looking statements due to a variety of risks and uncertainties, which include, without limitation, risks and uncertainties related to Alumis' ability to advance ESK-001 and its other clinical candidates and to obtain regulatory approval of and ultimately commercialize Alumis' clinical candidates, the timing and results of preclinical and clinical trials, Alumis' ability to fund development activities and achieve development goals, Alumis' ability to protect its intellectual property and other risks and uncertainties described in Alumis' filings with the Securities and Exchange Commission (SEC), including those described from time to time under the caption "Risk Factors" and elsewhere in Alumis' current and future reports filed with the SEC, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2024. Alumis explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

ALUMIS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(in thousands)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Operating expenses:				
Research and development expenses	$ 87,824	$ 37,788	$ 178,350	$ 103,071
General and administrative expenses	10,575	5,971	23,782	14,971
Total operating expenses	98,399	43,759	202,132	118,042
Loss from operations	(98,399)	(43,759)	(202,132)	(118,042)
Other income (expense):				
Interest income	5,322	951	8,153	2,509
Change in fair value of derivative liability	—	(551)	(5,406)	(119)
Other income (expense), net	(40)	(18)	(89)	(41)
Total other income (expense), net	5,282	382	2,658	2,349
Net loss	$ (93,117)	$ (43,377)	$ (199,474)	$ (115,693)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities, net	140	(3)	137	127
Net loss and other comprehensive loss	$ (92,977)	$ (43,380)	$ (199,337)	$ (115,566)

ALUMIS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

(in thousands)	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 213,417	$ 45,996
Restricted cash	—	113
Marketable securities	148,453	2,956
Research and development prepaid expenses	12,241	2,661
Other prepaid expenses and current assets	3,236	1,631
Total current assets	377,347	53,357

Restricted cash, non-current	1,024	1,024
Property and equipment, net	21,429	22,441
Operating lease right-of-use assets, net	12,752	12,783
Other long-term assets	7	7
Total assets	$ 412,559	$ 89,612
Liabilities, Redeemable Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,444	$ 1,118
Research and development accrued expenses	18,140	10,946
Other accrued expenses and current liabilities	7,464	7,087
Operating lease liabilities, current	1,467	1,720
Total current liabilities	33,515	20,871
Operating lease liabilities, non-current	29,631	30,860
Share repurchase liability	1,024	1,771
Total liabilities	64,170	53,502
Redeemable convertible preferred stock	—	375,370
Stockholders' equity (deficit)		
Preferred stock	—	—
Common stock	5	1
Additional paid-in-capital	912,037	25,055
Accumulated other comprehensive income	139	2
Accumulated deficit	(563,792)	(364,318)
Total stockholders' equity (deficit)	348,389	(339,260)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 412,559	$ 89,612

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