# ALX Oncology Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Clinical Development and Operational Highlights and Upcoming Milestones

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SOUTH SAN FRANCISCO, Calif., March 09, 2023 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., (“ALX Oncology”) (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today reported financial results for the fourth quarter and year ended December 31, 2022 and provided clinical development and operational highlights.

“2022 was a productive year for us, with numerous clinical and corporate development accomplishments highlighted by the advancement of our lead program, evorpacept, for the treatment of multiple solid tumor indications and hematological malignancies. We also expanded evorpacept into new indications and combinations,” said Dr Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology. “These included a Phase 1 trial in urothelial cancer (“UC”) in combination with PADCEV®, and a new investigational treatment arm in the I-SPY-P1 trial for the treatment of patients with unresectable or metastatic HER2-positive and HER2-low breast cancer in combination with ENHERTU® in partnership with Quantum Leap Healthcare Collaborative.”

Dr. Pons added, “2023 is expected to be an eventful year for ALX Oncology with the presentation of data from ASPEN-06, a randomized Phase 2 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-positive gastric/gastroesophageal junction (“GEJ”) cancer in the second half of 2023, and the presentation of dose optimization results from ASPEN-02, a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with myelodysplastic syndromes (“MDS”) in the second half of 2023. Additionally, we are on track to file an Investigational New Drug (“IND”) application in the first half of 2023, in collaboration with Tallac Therapeutics, for ALTA-002 that will further expand our clinical pipeline beyond evorpacept.”

**Anticipated Key Milestones in 2023**

- Presentation of data from a randomized Phase 2 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-positive gastric/GEJ cancer (ASPEN-06) in the second half of 2023.
- Presentation of dose optimization results of a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with MDS (ASPEN-02) in the second half of 2023.
- Initiation of a Phase 1b dose optimization clinical trial of evorpacept in combination with azacitidine and venetoclax for the treatment of patients with relapsed or refractory (“r/r”) or newly diagnosed (“ND”) acute myeloid leukemia (“AML”) (ASPEN-05) in the second half of 2023.
- Filing an IND for ALTA-002, a SIRPα Toll-like receptor agonist antibody conjugate in collaboration with Tallac Therapeutics in the first half of 2023.
- Expansion of the antibody-drug conjugate (“ADC”) platform acquired from ScalmiBio to identify clinical development candidates by the second half of 2023.

**Recent Clinical Developments for Evorpacept**

- **First patient dosed in ASPEN-07 study evaluating evorpacept in combination with PADCEV® (enfortumab vedotin-ejfv), an ADC, in patients with UC.**
  - In February 2023, ALX Oncology announced the first patient was dosed in the Phase 1 ASPEN-07 study evaluating evorpacept in combination with enfortumab vedotin-ejfv, an ADC, in patients with UC. ASPEN-07 is a phase 1, open-label, multi-center study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of evorpacept in combination with enfortumab vedotin-ejfv in subjects with unresectable locally advanced or metastatic UC.
- **Presented initial clinical data from the Phase 1a dose escalation portion of the ASPEN-05 trial evaluating evorpacept in combination with azacitidine and venetoclax for the treatment of patients with r/r or ND AML at American Society of Hematology (“ASH”).**
  - In December 2022, ALX Oncology presented a poster presentation at ASH showing that the combination of evorpacept with azacitidine and venetoclax is active and generally well tolerated. As of October 3, 2022, 14 patients with either r/r or ND AML have been treated with evorpacept in the Phase 1 dose escalation part of the study, administered at 20 mg/kg or 30 mg/kg once every 2 weeks or 60 mg/kg once every 4 weeks (“Q4W”) together with standard dosing of azacitidine and venetoclax.
  - Evorpacept in combination with azacitidine and venetoclax was generally well tolerated (N=14) with no maximum tolerated dose identified and a maximum administered dose of 60 mg/kg Q4W. In 10 relapsed or refractory AML

response-evaluable patients, including 8 that had progressed after prior venetoclax treatment, all experienced a reduction in bone marrow blasts, and 4 achieved a response. In 3 newly diagnosed AML response-evaluable patients, all 3 achieved a response, including 1 complete response ("CR"), 1 CR with incomplete hematologic recovery, and 1 morphologic leukemia free state.

- **Presented data from ASPEN-03 and ASPEN-04, the Company's Phase 2 head and neck squamous cell carcinoma ("HNSCC") studies at Society for Immunotherapy of Cancer ("SITC").**
    - In November 2022, ALX Oncology presented two Trials in Progress abstracts at SITC related to ASPEN-03 and ASPEN-04. ALX Oncology continues to advance ASPEN-03 and ASPEN-04, which are two distinct randomized Phase 2 studies for the treatment of patients with advanced HNSCC in combination with pembrolizumab with or without chemotherapy. Patient enrollment for ASPEN-03 and ASPEN-04 continues as planned.

**Recent Corporate Updates**

- In October 2022, ALX Oncology entered into a loan facility with Oxford Finance LLC and Silicon Valley Bank for up to $100 million of non-dilutive financing. Under the terms of the loan agreement, ALX Oncology drew $10 million of an initial $50 million tranche at closing, with the remaining $40 million available at its discretion through the end of 2023. ALX Oncology also has access up to an additional $50 million with $12.5 million available in each of two tranches based upon the achievement of milestones related to the development of evorpacept and one pre-clinical product candidate, and $25 million available at the Lenders' discretion.
- In November 2022, strengthened board of directors by adding an additional independent board member with significant operational and commercial leadership experience in the biopharmaceutical industry:
    - Scott Garland, currently strategic advisor and member of the board of directors at Pact Pharma and previously Chief Executive Officer of Portola Pharmaceuticals, has more than 30 years of biopharmaceutical industry knowledge and brings deep commercial and executive leadership experience.

**Full Year and Fourth Quarter 2022 Financial Results:**

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of December 31, 2022 were $282.9 million. ALX Oncology believes its cash, cash equivalents, investments and the ability to draw down up to an additional $40 million of its term loan are sufficient to fund planned operations through mid-2025.
- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of the Company's current lead product candidate, evorpacept, and R&D employee-related expenses. These expenses for the three months ended December 31, 2022 were $25.2 million, compared to $20.9 million for the prior-year period. R&D expenses for the year ended December 31, 2022 were $98.4 million, compared to $60.2 million for the prior-year period.
- **General and Administrative ("G&A") Expenses:** G&A expenses consist primarily of administrative employee-related expenses, legal and other professional fees, patent filing and maintenance fees, and insurance. These expenses for the three months ended December 31, 2022 were $7.0 million, compared to $7.6 million for the prior-year period. G&A expenses for the year ended December 31, 2022 were $29.0 million, compared to $23.4 million for the prior-year period.
- **Net loss:** GAAP net loss was $30.7 million for the fourth quarter ended December 31, 2022, or $0.75 per basic and diluted share, as compared to a net loss of $28.4 million for the fourth quarter ended December 31, 2021, or $0.70 per basic and diluted share. GAAP net loss for the year ended December 31, 2022 was $123.5 million, or $3.03 per basic and diluted share, as compared to $83.5 million, or $2.07 per basic and diluted share, for the year ended December 31, 2021. Non-GAAP net loss was $24.4 million for the fourth quarter ended December 31, 2022, as compared to a net loss of $22.8 million for the fourth quarter ended December 31, 2021. Non-GAAP net loss for the year ended December 31, 2022 was $99.6 million, as compared to $69.5 million for the year ended December 31, 2021. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.

**About ALX Oncology**

ALX Oncology is a clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 checkpoint pathway and bridge the innate and adaptive immune system. ALX Oncology's lead candidate, evorpacept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. Evorpacept has demonstrated promising clinical responses across a range of hematologic and solid malignancies in combination with a number of commercial anti-cancer agents. ALX Oncology intends to continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignancies.

**Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements regarding future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, plans and objects of management for future operations, as well as statements regarding industry trends. Such forward-looking statements are based on ALX Oncology's beliefs and assumptions and on information currently available to it on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause ALX Oncology's actual results, performance or achievements to be materially

different from those expressed or implied by the forward-looking statements. These and other risks are described more fully in ALX Oncology's filings with the Securities and Exchange Commission ("SEC"), including ALX Oncology's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents ALX Oncology files with the SEC from time to time. Except to the extent required by law, ALX Oncology undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**ALX ONCOLOGY HOLDINGS INC.**
**Consolidated Statements of Operations**
(unaudited for the three months ended December 31, 2022 and 2021)
(in thousands, except share and per share amounts)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 25,197 | $ 20,894 | $ 98,400 | $ 60,170 |
| General and administrative | 7,022 | 7,578 | 29,036 | 23,385 |
| Total operating expenses | 32,219 | 28,472 | 127,436 | 83,555 |
| Loss from operations | (32,219) | (28,472) | (127,436) | (83,555) |
| Interest income | 1,807 | 21 | 4,278 | 91 |
| Other expense, net | (233) | (8) | (260) | (20) |
| Loss before income taxes | (30,645) | (28,459) | (123,418) | (83,484) |
| Income tax (provision) benefit | (64) | 21 | (64) | 21 |
| Net loss | $ (30,709) | $ (28,438) | $ (123,482) | $ (83,463) |
| Net loss per share, basic and diluted | $ (0.75) | $ (0.70) | $ (3.03) | $ (2.07) |
| Weighted-average shares of common stock used to compute net loss per shares, basic and diluted | 40,755,520 | 40,527,314 | 40,699,612 | 40,308,050 |

**Consolidated Balance Sheet Data**
(in thousands)

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cash, cash equivalents and investments | $ 282,906 | $ 363,667 |
| Total assets | $ 306,489 | $ 380,183 |
| Total liabilities | $ 43,025 | $ 17,134 |
| Accumulated deficit | $ (325,467) | $ (201,985) |
| Total stockholders' equity | $ 263,464 | $ 363,049 |

**GAAP to Non-GAAP Reconciliation**
(unaudited)
(in thousands)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| GAAP net loss, as reported | $ (30,709) | $ (28,438) | $ (123,482) | $ (83,463) |
| Adjustments: | | | | |
| Stock-based compensation expense | 6,295 | 5,686 | 23,839 | 13,914 |
| Accretion of term loan | 44 | — | 44 | — |
| Total adjustments | 6,339 | 5,686 | 23,883 | 13,914 |
| Non-GAAP net loss | $ (24,370) | $ (22,752) | $ (99,599) | $ (69,549) |

**Use of Non-GAAP Financial Measures**

We supplement our consolidated financial statements presented on a GAAP basis by providing additional measures which may be considered "non-GAAP" financial measures under applicable SEC rules. We believe that the disclosure of these non-GAAP financial measures provides our investors with additional information that reflects the amounts and financial basis upon which our management assesses and operates our business. These non-GAAP financial measures are not in accordance with generally accepted accounting principles and should not be viewed in isolation or as a substitute for reported, or GAAP, net loss, and are not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

“Non-GAAP net loss” is not based on any standardized methodology prescribed by GAAP and represent GAAP net loss adjusted to exclude stock-based compensation expense. Non-GAAP financial measures used by ALX Oncology may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies.

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