Olema Oncology Reports Fourth Quarter and Full-Year 2022 Financial Results and Provides Strategic Update

March 9, 2023

- *Significant progress made advancing lead program, OP-1250, with more than 170 patients treated to date*
- *Initiating first pivotal Phase 3 monotherapy clinical trial of OP-1250 in second- and third-line metastatic breast cancer in the second half of 2023*
- *Corporate restructuring and portfolio prioritization to focus on the late-stage clinical development of OP-1250*
- *Cash, cash equivalents and marketable securities of $204.4 million as of December 31, 2022, expected to fund operations into 2025*

SAN FRANCISCO, March 09, 2023 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. (“Olema”, “Olema Oncology”, Nasdaq: OLMA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted therapies for women’s cancers, today reported financial results for the fourth quarter and full-year ended December 31, 2022, and provided a strategic update.

“2022 was a successful year for Olema as we generated important clinical data advancing the opportunity for OP-1250, our complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD), as both a monotherapy and in combination with a CDK4/6 inhibitor. We continue to have confidence in OP-1250’s ability to become a best-in-class treatment option for ER+/HER2- metastatic breast cancer,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “We are committed to realizing the full potential of OP-1250, which we believe has demonstrated a clear, differentiated advantage as a complete ER antagonist and the potential endocrine therapy of choice. Given the challenging equity market environment, we made some difficult decisions regarding our organization and earlier-stage programs. As we sharpen our focus on the late-stage clinical development of OP-1250, we remain steadfast in our goal of bringing this potentially transformative therapy to women living with breast cancer.”

Olema’s restructuring announced today is the result of a strategic decision to focus resources on the late-stage clinical development of OP-1250, which includes the initiation of the company’s first pivotal Phase 3 trial in the second half of this year. As a result of the restructuring, Olema’s workforce will be reduced by approximately 25%, affecting employees across research, early development, and general and administrative functions. Chief Business Officer Kinney Horn will be departing the company, and Cyrus Harmon, Ph.D., co-founder of Olema, will step down from his role as the Chief Research Officer and remain a member of Olema’s Board of Directors.

“I am grateful to our employees for their strong commitment to our mission and dedication to patients. I would like to thank Kinney for his important contributions to Olema since joining in 2020, and we wish him well in his future endeavors,” continued Dr. Bohen. “Cyrus, who is a co-founder of Olema, has been an inspirational leader and was instrumental in the discovery and early development of OP-1250. His continued guidance as a member of the Board will be vital as we progress OP-1250 though late-stage development.”

2022 Corporate Highlights

- Presented clinical results from a Phase 1/2 clinical study of OP-1250 at the 34th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2022), which demonstrated that, across 68 heavily pre-treated patients, OP-1250 was well tolerated with attractive pharmacokinetics and sustained drug exposure levels approximately 20 times that of fulvestrant at the 120 mg daily dose. In addition, OP-1250 demonstrated strong anti-tumor activity, with 41% of patients seeing reductions in target tumor lesions, and durable benefit with a 39% clinical benefit rate (CBR) at the 120 mg dose level on a maturing dataset. Six partial responses (four confirmed and two unconfirmed) were observed in 57 efficacy-evaluable patients.
- Presented clinical results from a Phase 1b combination study at the 2022 San Antonio Breast Cancer Symposium (SABCS), which demonstrated OP-1250’s combinability with palbociclib with a tolerability profile consistent with palbociclib in combination with an aromatase inhibitor or fulvestrant, no drug-drug interaction, and no induced metabolism of palbociclib.
- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for OP-1250 for the treatment of ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor.

- Initiated a Phase 1b combination study with CDK4/6 inhibitor, ribociclib, and phosphoinositide 3-kinase alpha (PI3Ka) inhibitor, alpelisib.
- Announced an exclusive global license agreement with Aurigene Discovery Technologies Limited (Aurigene) to research, develop and commercialize novel small molecule inhibitors of an undisclosed oncology target.

Anticipated Upcoming Milestones

- Initiate a pivotal Phase 3 monotherapy clinical trial in the second- and third-line setting of ER+/HER2- advanced or metastatic breast cancer in the second half of 2023.
- Present Phase 2 combination with CDK4/6 inhibitor (palbociclib) clinical study results in the second quarter of 2023.
- Present Phase 2 monotherapy clinical study results in the second half of 2023.
- Present Phase 1b combination with CDK4/6 inhibitor (ribociclib) clinical study results in the second half of 2023.

Fourth Quarter and Full-Year 2022 Financial Results

Cash, cash equivalents and marketable securities as of December 31, 2022, were $204.4 million. Olema anticipates that this balance will be sufficient to fund operations into 2025.

Net loss was $26.2 million and $104.8 million for the quarter and year ended December 31, 2022, respectively, as compared to $21.6 million and $71.1 million for the quarter and year ended December 31, 2021, respectively. The increase in net loss related primarily to Olema's continued investment in OP-1250, increased spending on research and development activities including an $8.0 million upfront payment to Aurigene in the second quarter, and an increase in general and administrative (G&A) costs.

GAAP research and development (R&D) expenses were $21.6 million and $82.3 million for the quarter and year ended December 31, 2022, respectively, as compared to $16.0 million and $51.1 million for the quarter and year ended December 31, 2021, respectively. The increase in R&D expenses was primarily related to increases in advancing ongoing clinical studies of OP-1250 and associated manufacturing costs, nonclinical research and discovery program activities, including an $8.0 million upfront payment to Aurigene in the second quarter, and personnel-related expenses due to higher headcount, including non-cash stock-based compensation expenses.

Non-GAAP R&D expenses were $18.2 million and $69.8 million for the quarter and year ended December 31, 2022, respectively, excluding $3.4 million and $12.5 million non-cash stock-based compensation expense, respectively. Non-GAAP R&D expenses were $13.1 million and $41.8 million for the quarter and year ended December 31, 2021, respectively, excluding $2.9 million and $9.3 million non-cash stock-based compensation expense, respectively. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found at the end of this press release.

GAAP G&A expenses were $5.6 million and $24.7 million for the quarter and year ended December 31, 2022, respectively, as compared to $5.8 million and $20.4 million for the quarter and year ended December 31, 2021, respectively. The increase in G&A expenses was primarily related to increases in personnel-related expenses due to higher headcount, including non-cash stock-based compensation expense, and public company-related expenses, including legal compliance and other corporate costs.

Non-GAAP G&A expenses were $4.1 million and $18.3 million for the quarter and year ended December 31, 2022, respectively, excluding $1.5 million and $6.4 million non-cash stock-based compensation expense respectively. Non-GAAP G&A expenses were $4.1 million and $13.8 million for the quarter and year ended December 31, 2021, excluding $1.7 million and $6.6 million non-cash stock-based compensation expense, respectively. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found at the end of this press release.

About Olema Oncology

Olema Oncology is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted therapies for women's cancers. Olema's lead product candidate, OP-1250, is a proprietary, orally-available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD). It is currently being evaluated both as a single agent in an ongoing Phase 2 clinical trial, and in combination with CDK4/6 inhibitors (palbociclib and ribociclib) and a PI3Ka inhibitor (alpelisib), in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. OP-1250 has been granted FDA Fast Track designation for the treatment of ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts.

Non-GAAP Financial Information

The results presented in this press release include both GAAP information and non-GAAP information. As used in this release, non-GAAP R&D expense is defined by Olema as GAAP R&D expense excluding stock-based compensation expense, and non-GAAP G&A expense is defined by Olema as GAAP G&A expense excluding stock-based compensation expense. We use these non-GAAP financial measures to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool, and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. Other companies, including companies in our industry, may calculate similarly titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures and not rely on any single financial measure to evaluate our business.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of

Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Words such as “anticipate,” “expect,” “will,” “may,” “goal,” “potential” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements include those related to the company’s financial condition, results of operations, cash position, the sufficiency of the company’s financial resources, anticipated timing, expenses, cost savings and results of the company’s strategic restructuring, continued service on the Board of Directors by Dr. Harmon, potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of OP-1250, the potential of OP-1250 to become a best-in-class treatment option for ER+/HER2- metastatic breast cancer, the endocrine therapy of choice and a transformative therapy for women living with breast cancer, the development of OP-1250, OP-1250’s combinability with other drugs, and the timelines for clinical trials of OP-1250 as a monotherapy and in combination trials. Because such statements deal with future events and are based on Olema’s current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of Olema could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, those discussed in the section titled “Risk Factors” in Olema’s Annual Report on Form 10-K for the year ended December 31, 2022, and future filings and reports that Olema makes from time to time with the U.S. Securities and Exchange Commission. Except as required by law, Olema assumes no obligation to update these forward-looking statements or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

Olema Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 204,421	$ 287,250
Total assets	**$ 215,645**	**$ 295,945**
Total current liabilities	$ 16,549	$ 9,019
Total liabilities	$ 18,099	$ 11,377
Total stockholders’ equity	$ 197,546	$ 284,568
Total liabilities and stockholders’ equity	**$ 215,645**	**$ 295,945**

Olema Pharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development (1) (3)	$ 21,584	$ 15,975	$ 82,274	$ 51,100
General and administrative (2)	5,635	5,782	24,714	20,391
Total operating expenses	27,219	21,757	106,988	71,491
Loss from operations	(27,219)	(21,757)	(106,988)	(71,491)
Other income (expense):				
Interest income	973	109	2,228	442
Other income (expense)	67	10	(27)	(47)
Total other income	1,040	119	2,201	395
Net loss	$ (26,179)	$ (21,638)	$ (104,787)	$ (71,096)
Net loss per share, basic and diluted	$ (0.65)	$ (0.54)	$ (2.62)	$ (1.80)
Weighted average shares used to compute net loss per share, basic and diluted	40,188,466	39,742,723	39,995,460	39,524,272

Reconciliation of GAAP to Non-GAAP Information
(In thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
(1) Research and development reconciliation				
GAAP research and development (3)	$ 21,584	$ 15,975	$ 82,274	$ 51,100
Less: share-based compensation expense	3,374	2,919	12,462	9,346

Non-GAAP research and development	**$ 18,210**	**$ 13,056**	**$ 69,812**	**$ 41,754**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 5,635	$ 5,782	$ 24,714	$ 20,391
Less: share-based compensation expense	1,487	1,708	6,367	6,567
Non-GAAP general and administrative	**$ 4,148**	**$ 4,074**	**$ 18,347**	**$ 13,824**

(3) Research and development expenses for the twelve-months ended December 31, 2022 include an $8.0 million upfront payment in connection to the Aurigene Agreement.

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