Olema Oncology Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 8, 2022

- *Presented preliminary results from OP-1250 Phase 1/2 dose expansion study demonstrating favorable tolerability, high drug exposure, and strong anti-tumor activity at the 34th EORTC-NCI-AACR Symposium*
- *Initial clinical data for OP-1250 in combination with CDK 4/6 inhibitor, palbociclib, to be presented at the 2022 San Antonio Breast Cancer Symposium (SABCS)*
- *First pivotal monotherapy Phase 3 study initiation planned for mid-2023*
- *Strong cash, cash equivalents and marketable securities position of $222.6 million as of September 30, 2022, sufficient to support execution of clinical, research and operational goals into the second half of 2024*

SAN FRANCISCO, Nov. 08, 2022 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. ("Olema" or "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 third quarter financial results for the period ended September 30, 2022, and provided a business update.

"On the heels of presenting our preliminary monotherapy dose expansion study results at ENA 2022, and with initial combination study data coming later this quarter at SABCS, we believe OP-1250 has shown itself to be a highly differentiated CERAN/SERD that completely shuts down estrogen receptor (ER) transcriptional activity in both wild-type and ESR1 mutant receptors," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "We have been granted Fast Track designation from the FDA in second- and third-line ER+/HER2- metastatic breast cancer, and we are rapidly generating more data in support of initiating our first pivotal Phase 3 monotherapy study mid-next year. As we enter the next stage of development and with an evolving competitive landscape, we are driven to continue our mission to improve outcomes for women living with cancer."

Recent Corporate Highlights

- Presented preliminary 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) in Barcelona, Spain.
- Study results demonstrated that across 68 heavily pre-treated patients at 60 mg and 120 mg once daily oral doses, OP-1250 was well tolerated with attractive pharmacokinetics (PK) and sustained drug exposure levels approximately 20 times that of fulvestrant at the 120 mg dose. In addition, OP-1250 demonstrated strong anti-tumor activity, with 41% of patients seeing reductions in target tumor lesions, and durable benefit. Six partial responses (four confirmed and two unconfirmed) were observed in 57 efficacy-evaluable patients.
- Following the selection of RP2D based on pharmacokinetics, safety and tolerability, and encouraging early anti-tumor activity, the Phase 2 monotherapy study is rapidly advancing with primary cohorts fully enrolled: patients with measurable disease (N=50) and patients with non-measurable disease (N=15).
- Dose escalation in the Phase 1b combination study with the CDK4/6 inhibitor palbociclib has completed, with Phase 2 dose expansion at 120 mg of OP-1250 in combination with palbociclib now ongoing. Combinability has been demonstrated across the completed dose escalation cohorts (30 mg, 60 mg, 90 mg, and 120 mg of OP-1250), including no dose limiting toxicities, no change in exposure of palbociclib or OP-1250, and overall tolerability consistent with the expected profile of palbociclib plus an endocrine therapy.
- Initiated Phase 1b combination study with CDK 4/6 inhibitor, ribociclib, and phosphoinositide 3-kinase alpha (PI3Ka) inhibitor, alpelisib.

Anticipated Milestones

- Present preliminary Phase 1b dose escalation study data in combination with CDK4/6 inhibitor, palbociclib, at the 2022 San Antonio Breast Cancer Symposium in December.
- Continue combination studies with CDK4/6 inhibitors, palbociclib and ribociclib, and PI3Ka inhibitor, alpelisib.
- Present additional monotherapy and combination therapy data in 2023.

- Initiate pivotal Phase 3 monotherapy study in the second/third-line ER+/HER2- advanced or metastatic breast cancer in mid-2023.

Financial Results

- Cash, cash equivalents and marketable securities as of September 30, 2022, were $222.6 million. Olema anticipates that this balance will be sufficient to fund operations into the second half of 2024.
- Net loss for the quarter ended September 30, 2022, was $22.7 million, compared to $17.7 million for the same period of the prior year. The increase in net loss related primarily to Olema's continued investment in OP-1250, increased spending on research and development activities, and an increase in general and administrative (G&A) costs.
- GAAP research and development (R&D) expenses were $17.6 million for the quarter ended September 30, 2022, compared to $12.5 million for the same period of the prior year. The increase in R&D expenses was primarily related to the advancement of the development program for OP-1250 and an increase in nonclinical research and discovery program activities. Non-GAAP R&D expenses were $14.8 million for the quarter ended September 30, 2022, excluding $2.8 million of non-cash stock-based compensation expense. Non-GAAP R&D expenses were $10.1 million for the quarter ended September 30, 2021, excluding $2.4 million of non-cash stock-based compensation expense. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found at the end of this news release.
- GAAP G&A expenses were $5.6 million for the quarter ended September 30, 2022, as compared to $5.2 million for the same period of the prior year. The increase in G&A expenses was primarily related to higher personnel-related expenses and other corporate costs. Non-GAAP G&A expenses were $4.1 million for the quarter ended September 30, 2022, excluding $1.5 million of non-cash stock-based compensation expense. Non-GAAP G&A expenses were $3.5 million for the quarter ended September 30, 2021, excluding $1.7 million of non-cash stock-based compensation expense.

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 CDK 4/6 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. 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 research and development expense is defined by Olema as GAAP research and development expense excluding stock-based compensation expense, and non-GAAP general and administrative expense is defined by Olema as GAAP general and administrative 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," "intend," "will," "may," "goal," "estimate," "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 potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of OP-1250, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, to be filed on November 8, 2022, and future filings and reports that Olema makes from time to time with the United States 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)

September 30, 2022	December 31, 2021
(Unaudited)	*(*)*

Cash, cash equivalents and marketable securities	$ 222,600	$ 287,250
Total assets	**$ 231,997**	**$ 295,945**
Total current liabilities	$ 12,552	$ 9,019
Total liabilities	$ 14,298	$ 11,377
Total stockholders' equity	$ 217,699	$ 284,568
Total liabilities and stockholders' equity	**$ 231,997**	**$ 295,945**

(*) Derived from audited financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
	(Unaudited)		*(Unaudited)*	
Operating expenses:				
Research and development (1) (3)	$ 17,627	$ 12,523	$ 60,690	$ 35,125
General and administrative (2)	5,595	5,239	19,079	14,609
Total operating expenses	23,222	17,762	79,769	49,734
Loss from operations	(23,222)	(17,762)	(79,769)	(49,734)
Other income (expense):				
Interest income	622	105	1,255	333
Other income (expense)	(120)	(56)	(94)	(57)
Total other income	502	49	1,161	276
Net loss	$ (22,720)	$ (17,713)	$ (78,608)	$ (49,458)
Net loss per share, basic and diluted	$ (0.57)	$ (0.45)	$ (1.97)	$ (1.25)
Weighted average shares used to compute net loss per share, basic and diluted	40,036,201	39,607,745	39,930,418	39,450,655

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
	(Unaudited)		*(Unaudited)*	
(1) Research and development reconciliation				
GAAP research and development (3)	$ 17,627	$ 12,523	$ 60,690	$ 35,125
Less: share-based compensation expense	2,812	2,405	9,088	6,427
Non-GAAP research and development	**$ 14,815**	**$ 10,118**	**$ 51,602**	**$ 28,698**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 5,595	$ 5,239	$ 19,079	$ 14,609
Less: share-based compensation expense	1,463	1,752	4,880	4,859
Non-GAAP general and administrative	**$ 4,132**	**$ 3,487**	**$ 14,199**	**$ 9,750**

(3) Research and development expenses for the nine-months periods ended September 30, 2022 include $8.0 million upfront payment in connection to the Aurigene Agreement.

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