Olema Oncology Reports Fourth Quarter and Full-Year 2023 Financial Results and Provides Corporate Update

Mar 11, 2024

- *Presented compelling clinical results for palazestrant both as a monotherapy and in combination with CDK4/6 inhibitors, ribociclib and palbociclib, in Q4 2023*
- *Initiated OPERA-01 pivotal Phase 3 monotherapy trial in Q4 2023; top-line results expected in 2026*
- *60-patient Phase 2 studies in combination with each of ribociclib and palbociclib are fully enrolled; palazestrant-ribociclib clinical update to be presented at ESMO Breast Cancer Annual Congress 2024, May 15-17, 2024, in Berlin*
- *Cash, cash equivalents and marketable securities of $261.8 million as of December 31, 2023*

SAN FRANCISCO, March 11, 2024 (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, 2023, and provided a corporate update.

"In 2023 we demonstrated the unique opportunity ahead for palazestrant to make a meaningful impact on improving treatment options for women with ER+/HER2- breast cancer. We believe palazestrant's activity on both wild-type and ESR1-mutant breast cancer, and its ability to safely combine with ribociclib, result in a highly differentiated profile amongst this emerging new class of estrogen receptor-targeting therapies," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "We have recently completed enrollment in our 60-patient Phase 2 study of 120 mg palazestrant in combination with 600 mg ribociclib, and we are looking forward to sharing an update on this study at the 2024 ESMO Breast Cancer Annual Congress. Beyond palazestrant, we recently declared a development candidate for our KAT6 program, OP-3136, and we are advancing towards an IND filing by the end of this year. Our mission at Olema is to improve the lives of women living with cancer and we are very pleased with the progress we are making."

Recent Corporate Highlights

- Presented interim clinical results of palazestrant in combination with CDK4/6 inhibitors ribociclib and palbociclib at the 2023 San Antonio Breast Cancer Symposium (SABCS), showing no significant drug-drug interaction, no dose-limiting toxicities and a tolerability profile consistent with the FDA-approved labels of ribociclib or palbociclib plus an endocrine therapy.
- Presented palazestrant monotherapy Phase 2 clinical results at the European Society for Medical Oncology (ESMO) Congress 2023 in Madrid, Spain, as an oral presentation demonstrating compelling activity in both wild-type and ESR1-mutant tumor types.
- Initiated OPERA-01, our pivotal Phase 3 monotherapy clinical trial in the second- and third-line setting of ER+/HER2- advanced or metastatic breast cancer, including dosing first patients and activating multiple trial sites globally.
- Nominated OP-3136, an orally bioavailable KAT6 inhibitor, as a development candidate. OP-3136 demonstrated potent anti-tumor activity alone and in combination with both palazestrant and CDK4/6 inhibitors in preclinical ER+ breast cancer models.
- Announced the expansion of Olema's clinical collaboration with Novartis Institutes for BioMedical Research, Inc. (Novartis), increasing the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib to approximately 60 patients. This study is fully enrolled.
- Completed a combined financing for up to $180 million including an equity private placement of approximately $130 million of common stock as well as a new senior secured credit facility with an aggregate principal amount of up to $50 million with Silicon Valley Bank (SVB), $25 million of which is currently available.

Upcoming Milestones

- Present interim Phase 2 clinical results of palazestrant in combination with ribociclib at ESMO Breast Cancer Annual Congress 2024, May 15-17, 2024, in Berlin, Germany.

- Initiate Phase 1b/2 clinical study of palazestrant in combination with mTOR inhibitor, everolimus, in Q3 2024.
- File an Investigational New Drug, or IND, application with the FDA for OP-3136, a KAT6 inhibitor, in late 2024, and advance clinical development.
- Prepare for pivotal Phase 3 first-line trial in combination with CDK4/6 inhibitor, ribociclib.

Fourth Quarter and Full-Year 2023 Financial Results

Cash, cash equivalents and marketable securities as of December 31, 2023, were $261.8 million.

Net loss was $26.8 million and $96.7 million for the quarter and year ended December 31, 2023, respectively, as compared to $26.2 million and $104.8 million for the quarter and year ended December 31, 2022, respectively. The increase in net loss for the fourth quarter was primarily related to increased spending on clinical operations and development-related activities, including personnel-related expenses, as Olema continues to advance palazestrant into late-stage clinical trials. This increase was offset by decreased spending on general and administrative activities and higher interest income earned from marketable securities. The decrease in net loss for the full year 2023 was primarily due to higher interest income earned from marketable securities.

GAAP research and development (R&D) expenses were $25.9 million and $86.1 million for the quarter and year ended December 31, 2023, respectively, as compared to $21.6 million and $82.3 million for the quarter and year ended December 31, 2022, respectively. The increase in R&D expenses was primarily a result of increased spending on clinical operations and development-related activities including personnel-related costs as Olema continues to advance palazestrant into late-stage clinical development, which were offset by decreased spending on research-related activities.

Non-GAAP R&D expenses were $23.0 million and $74.4 million for the quarter and year ended December 31, 2023, respectively, excluding $2.9 million and $11.8 million non-cash stock-based compensation expense, respectively. 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. 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 $4.5 million and $18.8 million for the quarter and year ended December 31, 2023, respectively, as compared to $5.6 million and $24.7 million for the quarter and year ended December 31, 2022, respectively. The decrease in G&A expenses was primarily due to decreased spending on corporate- and legal-related costs, and personnel-related expenses.

Non-GAAP G&A expenses were $3.1 million and $13.3 million for the quarter and year ended December 31, 2023, respectively, excluding $1.4 million and $5.5 million non-cash stock-based compensation expense respectively. Non-GAAP G&A expenses were $4.1 million and $18.3 million for the quarter and year ended December 31, 2022, excluding $1.5 million and $6.4 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 Palazestrant (OP-1250)

Palazestrant (OP-1250) is a novel, orally-available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD). It is currently being investigated in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. In clinical studies, palazestrant completely blocks ER-driven transcriptional activity in both wild-type and mutant forms of metastatic ER+ breast cancer and has demonstrated anti-tumor activity along with attractive pharmacokinetics and exposure, favorable tolerability, CNS penetration, and combinability with CDK4/6 inhibitors. Palazestrant has been granted U.S. Food and Drug Administration (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. It is currently being evaluated both as a single agent in an ongoing Phase 3 clinical trial, OPERA-01, and in Phase 2 combination studies with CDK4/6 inhibitors (palbociclib and ribociclib) and a PI3Ka inhibitor (alpelisib). For more information, please visit www.opera01study.com.

About Olema Oncology

Olema Oncology is a clinical-stage biopharmaceutical company committed to transforming the standard of care and improving outcomes for women living with cancer. Olema is advancing a pipeline of novel therapies by leveraging our deep understanding of endocrine-driven cancers, nuclear receptors, and mechanisms of acquired resistance. In addition to our lead product candidate, palazestrant (OP-1250), a proprietary, orally-available complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), Olema is developing a potent KAT6 inhibitor. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit us at www.olema.com.

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,” "believe," “could,”

"expect," "goal," "may," "potential," "will" 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 Olema's financial condition and resources, results of operations, cash position, the timeline of Olema's pivotal Phase 3 monotherapy clinical trial (OPERA-01), the timelines for initiation and enrollment for potential clinical studies and for results of clinical trials of palazestrant (OP-1250) as a monotherapy and in combination trials, potential beneficial characteristics, including but not limited to safety, tolerability, efficacy and therapeutic effects of palazestrant, the potential of palazestrant to improve treatment options or outcomes for women living with ER+/HER2- breast cancer, palazestrant's combinability with other drugs, and the sufficiency and timing of Olema's preclinical program, including the potential beneficial characteristics of its KAT6 inhibitor compounds, its applicability to breast and other cancers and the timing of a potential IND application. 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, 2023, 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, including in the event that actual results differ materially from those anticipated in the forward-looking statements.

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 261,807	$ 204,421
Total assets	**276,945**	**215,645**
Total current liabilities	21,621	16,549
Total liabilities	23,050	18,099
Total stockholders' equity	253,895	197,546
Total liabilities and stockholders' equity	**$ 276,945**	**$ 215,645**

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development (1)	$ 25,872	$ 21,584	$ 86,140	$ 82,274
General and administrative (2)	4,544	5,635	18,821	24,714
Total operating expenses	30,416	27,219	104,961	106,988
Loss from operations	(30,416)	(27,219)	(104,961)	(106,988)
Other income (expense):				
Interest income	3,551	973	8,325	2,228
Other income (expense):	93	67	(19)	(27)
Total other income	3,644	1,040	8,306	2,201
Net loss	$ (26,772)	$ (26,179)	$ (96,655)	$ (104,787)
Net loss per share, basic and diluted	$ (0.49)	$ (0.65)	$ (2.14)	$ (2.62)
Weighted average shares used to compute net loss per share, basic and diluted	54,783,945	40,188,466	45,247,098	39,995,460

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
(1) Research and development reconciliation				
GAAP research and development (3)	$ 25,872	$ 21,584	$ 86,140	$ 82,274

Less: share-based compensation expense	2,911	3,374	11,769	12,462
Non-GAAP research and development	**$ 22,961**	**$ 18,210**	**$ 74,371**	**$ 69,812**

(2) General and administrative reconciliation				
GAAP general and administrative	$ 4,544	$ 5,635	$ 18,821	$ 24,714
Less: share-based compensation expense	1,440	1,487	5,487	6,367
Non-GAAP general and administrative	**$ 3,104**	**$ 4,148**	**$ 13,334**	**$ 18,347**

(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.

IR and Media Contact:
Geoffrey Mogilner, Vice President, Investor Relations and Communications
ir@olema.com