Olema Oncology Reports Second Quarter 2023 Financial Results and Provides Corporate Update

Aug 8, 2023

- *Initiation of OPERA-01 pivotal Phase 3 monotherapy clinical trial on track; expecting to enroll first patient in fourth quarter*
- *New clinical data for palazestrant (OP-1250) to be presented in the fourth quarter including both monotherapy and CDK4/6 inhibitor combination updates*
- *Cash, cash equivalents and marketable securities of $167.4 million as of June 30, 2023, expected to fund operations into the second quarter of 2025*

SAN FRANCISCO, Aug. 08, 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 second quarter ended June 30, 2023, and provided a corporate update.

“Olema is on track to deliver on significant milestones this year, including initiating our first pivotal Phase 3 trial, OPERA-01, which will test palazestrant (OP-1250) as a monotherapy in the second- and third-line metastatic setting, as well as presenting new data from our ongoing monotherapy and combination clinical studies,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “We are actively engaged in start-up activities for our OPERA-01 Phase 3 clinical trial, with enrollment expected to begin in the fourth quarter. Among other upcoming milestones, we look forward to presenting our mature Phase 2 monotherapy data as part of an oral presentation at the ESMO Congress in Madrid in October. Our goal with palazestrant remains to significantly improve upon current standard-of-care endocrine therapy as the backbone treatment for metastatic breast cancer.”

Recent Corporate Highlights

- Presented interim Phase 1b/2 clinical study results of palazestrant in combination with a CDK4/6 inhibitor (palbociclib) at the 2023 European Society for Medical Oncology (ESMO) Breast Cancer Annual Congress in Berlin, Germany. Results demonstrated no dose-limiting toxicities and no observed drug-drug interaction, with an overall tolerability profile of the combination consistent with the FDA-approved label of palbociclib plus an endocrine agent.
- Presented trials-in-progress poster from the ongoing Phase 1b/2 dose escalation and dose expansion study of palazestrant in combination with CDK4/6 inhibitor, ribociclib, or PI3Ka inhibitor, alpelisib, at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Upcoming Milestones

- Present palazestrant Phase 2 monotherapy clinical study results as an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2023 in Madrid, Spain, on October 22, 2023.
- Present palazestrant interim Phase 1b/2 clinical study results in combination with CDK4/6 inhibitor, palbociclib, in the fourth quarter of 2023.
- Present palazestrant interim Phase 1b clinical study results in combination with CDK4/6 inhibitor, ribociclib, in the fourth quarter of 2023.
- Initiate OPERA-01, Olema’s first pivotal Phase 3 clinical trial, testing palazestrant as a monotherapy in second- and third-line metastatic breast cancer, anticipated in the fourth quarter of 2023.

Second Quarter 2023 Financial Results

Cash, cash equivalents and marketable securities as of June 30, 2023, were $167.4 million, a reduction of approximately $18.6 million from the quarter ended March 31, 2023. Olema anticipates that this balance will be sufficient to fund operations into the second quarter of 2025.

Net loss for the quarter ended June 30, 2023, was $20.1 million, as compared to $32.9 million for the same period of the prior year. The decrease in net loss was primarily related to decreased spending on discovery research activities including a one-time upfront payment of $8.0 million to Aurigene Pharmaceuticals in June 2022 pursuant to the exclusive global license agreement entered into in June 2022 between the Company and Aurigene

Pharmaceuticals (the Aurigene Agreement), and general and administrative activities including a reduction in corporate- and legal-related costs, which were primarily offset by increased spending on clinical development and operations-related activities as we continue to advance palazestrant into late-stage clinical development.

GAAP research and development (R&D) expenses were $18.0 million for the quarter ended June 30, 2023, as compared to $27.1 million for the quarter ended June 30, 2022. The decrease was primarily due to decreased spending on (i) preclinical research programs, which included the $8.0 million upfront payment in connection with the Aurigene Agreement incurred and paid in June 2022, (ii) clinical pharmacology-related costs, and (iii) personnel-related expenses, which primarily related to lower headcount as a result of the restructuring and portfolio prioritization during the first quarter of 2023, and a decrease of approximately $0.2 million in non-cash stock-based compensation expense. Total decreases were primarily offset by increased spending on clinical operations-related activities as we continue to advance palazestrant into late-stage clinical trials.

Non-GAAP R&D expenses were $15.0 million for the quarter ended June 30, 2023, excluding $3.0 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were $23.8 million for the quarter ended June 30, 2022, excluding $3.2 million non-cash stock-based compensation expense. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found in the tables below.

GAAP general and administrative (G&A) expenses were $3.6 million for the quarter ended June 30, 2023, as compared to $6.2 million for the quarter ended June 30, 2022. The decrease in G&A expenses was primarily due to decreased spending on (i) corporate- and legal-related costs, and (ii) personnel-related expenses, primarily due to lower headcount as a result of the restructuring and portfolio prioritization, and a decrease of approximately $0.3 million in non-cash stock-based compensation expense.

Non-GAAP G&A expenses were $2.4 million for the quarter ended June 30, 2023, excluding $1.2 million non-cash stock-based compensation expense. Non-GAAP G&A expenses were $4.7 million for the quarter ended June 30, 2022, excluding $1.5 million non-cash stock-based compensation expense. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found in the tables below.

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, palazestrant (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. Palazestrant 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. For more information, please visit us at www.olema.com, or follow us on Twitter and LinkedIn.

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 non-cash 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 Olema's financial condition and resources, results of operations, cash position, the sufficiency of the initiation and timeline of Olema's pivotal Phase 3 monotherapy clinical trial (OPERA-01), the timelines for potential clinical study results and clinical trials of palazestrant (OP-1250) as a monotherapy and in combination trials, potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of palazestrant, the potential of palazestrant to significantly improve endocrine therapy for women living with ER+/HER2- metastatic breast cancer, and palazestrant's combinability with other drugs. 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 June 30, 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)

June 30, 2023	December 31, 2022

Cash, cash equivalents and marketable securities	$ 167,444	$ 204,421
Total assets	**177,624**	**215,645**
Total current liabilities	14,831	16,549
Total liabilities	16,041	18,099
Total stockholders' equity	161,583	197,546
Total liabilities and stockholders' equity	**$ 177,624**	**$ 215,645**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development (1)	$ 17,989	$ 27,054	$ 40,815	$ 43,063
General and administrative (2)	3,612	6,239	10,388	13,484
Total operating expenses	21,601	33,293	51,203	56,547
Loss from operations	(21,601)	(33,293)	(51,203)	(56,547)
Other income:				
Interest income	1,550	415	2,855	633
Other (expense) income	(44)	20	(33)	26
Total other income	1,506	435	2,822	659
Net loss	$ (20,095)	$ (32,858)	$ (48,381)	$ (55,888)
Net loss per share, basic and diluted	$ (0.49)	$ (0.82)	$ (1.20)	$ (1.40)
Weighted average shares used to compute net loss per share, basic and diluted	40,720,294	39,918,219	40,470,041	39,876,650

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
(1) Research and development reconciliation				
GAAP research and development	$ 17,989	$ 27,054	$ 40,815	$ 43,063
Less: share-based compensation expense	2,969	3,211	6,057	6,278
Non-GAAP research and development	**$ 15,020**	**$ 23,843**	**$ 34,758**	**$ 36,785**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 3,612	$ 6,239	$ 10,388	$ 13,484
Less: share-based compensation expense	1,201	1,517	2,743	3,415
Non-GAAP general and administrative	**$ 2,411**	**$ 4,722**	**$ 7,645**	**$ 10,069**

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