Olema Oncology Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

February 28, 2022

- *Presented Phase 1a proof-of-concept data for OP-1250 in metastatic, ER+ / HER2- breast cancer, with demonstrated attractive pharmacokinetics, favorable tolerability and encouraging anti-tumor activity in a heavily pretreated patient population*
- *Enrollment in Phase 1b dose expansion on track to complete in Q1 2022; Phase 2 to initiate in H1 2022*
- *Initiated Phase 1b combination study with palbociclib; Additional combination trials with CDK4/6 and PI3Kα inhibitors planned in 2022*
- *Appointed biotech industry veteran Naseem Zojwalla, M.D., as Chief Medical Officer*
- *Strong cash, cash equivalents and marketable securities position of $287.3 million as of December 31, 2021 sufficient to fund operations into 2024*

SAN FRANCISCO, Feb. 28, 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 financial results for the fourth quarter and full year ended December 31, 2021 and provided a business update.

"2021 was a transformative year for Olema. Our team made important progress against our strategic goals, culminating in the presentation of strong proof-of-concept data for OP-1250 in ER+ / HER2- breast cancer. The initial data, demonstrating OP-1250's attractive pharmacokinetics, favorable tolerability and encouraging anti-tumor activity in a heavily pretreated patient population, validate OP-1250's potential to become the endocrine therapy of choice for ER+ breast cancer. We are now actively expanding our clinical study enrollment and expect to be in a position to present more data later this year," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "Importantly, we entered 2022 with a strong balance sheet, and as we continue to build our team and grow our capabilities, we are well positioned to advance our clinical development program and discovery efforts."

Recent Corporate Highlights

- Presented interim Phase 1a dose escalation data for OP-1250 from the ongoing Phase 1/2 clinical study. The initial data provide strong proof-of-concept supporting OP-1250's potential as a once-daily oral monotherapy in women with recurrent, locally advanced, or metastatic ER+ / HER2- breast cancer, with OP-1250 demonstrating highly attractive pharmacokinetics, favorable tolerability, and clear efficacy signals in a heavily pretreated patient population.
- Initiated monotherapy dose expansion at 60 mg and 120 mg dose levels. Each cohort will enroll approximately 15 patients with measurable disease, and findings will help inform the selection of a recommended Phase 2 dose (RP2D). Enrollment remains on track to complete in the first quarter of 2022.
- Initiated Phase 1b combination study with palbociclib, a CDK4/6 inhibitor. The dose escalation portion of the combination trial includes a starting dose of 30 mg OP-1250 once-daily and follows a standard 3+3 design.
- Presented nonclinical data on OP-1250 in a poster session at the San Antonio Breast Cancer Symposium (SABCS), held December 7-10, 2021. Data presented showed that the addition of OP-1250 to anti-HER2 agents, trastuzumab and tucatinib, improved the inhibition of tumor growth in nonclinical models of ER+ / HER2+ breast cancer.
- Appointed Naseem Zojwalla, M.D., as Olema's new Chief Medical Officer. Dr. Zojwalla joins Olema from Turning Point Therapeutics and brings significant leadership in clinical development, operations and regulatory experience. Former CMO Pamela Klein, M.D., continues to work with Olema in a strategic advisory capacity and as a newly appointed member of the company's Scientific Advisory Board.
- In December 2021, Olema was added to the NASDAQ Biotechnology Index® (Nasdaq: NBI).

Anticipated Milestones

- Select the Recommended Phase 2 Dose (RP2D) for OP-1250 and initiate Phase 2 in the first half of 2022. The Phase 2 study includes enrollment across three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15) and patients with CNS metastasis (N=15).
- Initiate additional Phase 1b combination studies with CDK4/6 and PI3Kα inhibitors in 2022.
- Initiate Phase 1b study of OP-1250 in patients with ER+/HER2+ breast cancer and CNS metastases in the second half of 2022.
- Present updated monotherapy and initial combination data for OP-1250 in 2022.
- Sean Bohen, M.D., Ph.D., President and CEO of Olema Oncology, is scheduled to present at the 42nd Annual Cowen Healthcare Conference on Monday, March 7, 2022, at 2:50 PM ET.

Fourth Quarter and Full Year 2021 Financial Results

- Cash, cash equivalents and marketable securities as of December 31, 2021, were $287.3 million. Olema anticipates that this balance will be sufficient to fund operations into 2024.
- Net loss was $21.6 million and $71.1 million for the quarter and year ended December 31, 2021, respectively, as compared to $10.1 million and $22.1 million for the quarter and year ended December 31, 2020, respectively. The increase in net loss related primarily to Olema's continued investment in OP-1250, and an increase in general and administrative (G&A) infrastructure costs.
- GAAP research and development (R&D) expenses were $16.0 million and $51.1 million for the quarter and year ended December 31, 2021, respectively, as compared to $6.3 million and $13.7 million for the quarter and year ended December 31, 2020, respectively. The increase in R&D expenses was primarily related to the advancement of the ongoing Phase 1/2 clinical trial of OP-1250, increase in nonclinical development activities, higher personnel-related expenses and higher non-cash stock-based compensation expenses. 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. Non-GAAP R&D expenses were $4.8 million and $11.7 million for the quarter and year ended December 31, 2020, respectively, excluding $1.5 million and $2.0 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 news release.
- GAAP G&A expenses were $5.8 million and $20.4 million for the quarter and year ended December 31, 2021, respectively, as compared to $3.8 million and $7.8 million for the quarter and year ended December 31, 2020, respectively. The increase in G&A expenses was primarily related to an increase in personnel, public company-related expenses, other corporate costs and higher non-cash stock-based compensation expenses. Non-GAAP G&A expenses were $4.1 million and $13.8 million for the quarter and year ended December 31, 2021, respectively, excluding $1.7 million and $6.6 million non-cash stock-based compensation expense respectively. Non-GAAP G&A expenses were $3.0 million and $6.7 million for the quarter and year ended December 31, 2020, excluding $0.9 million and $1.1 million non-cash stock-based compensation expense respectively.

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 an orally-available small molecule with combined activity as both a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD). It is currently being evaluated as a single agent in an ongoing Phase 1/2 clinical trial, and in Phase 1b combination with palbociclib, in patients with recurrent, locally advanced, or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. 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 development of OP-1250, both as a monotherapy and in combination trials, including timelines related to data presentation, trial initiation and advancement, and enrollment, the beneficial characteristics, safety, efficacy and therapeutic effects of OP-1250, as well as the sufficiency of our financial resources and Olema being well positioned to advance its clinical development program and discovery efforts. 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, the risk that Olema's ongoing or future clinical studies in humans may show that OP-1250 is not a tolerable and effective treatment for breast cancer and other risks and uncertainties affecting Olema, as well as those discussed in the section titled "Risk Factors" in Olema's Annual Report

on Form 10-K for the year ended December 31, 2021 to be filed on February 28, 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)

	December 31, 2021	December 31, 2020
	(Audited)	*(Audited)*
Cash, cash equivalents and marketable securities	$ 287,250	$ 338,549
Total assets	**$ 295,945**	**$ 342,722**
Total current liabilities	$ 9,019	$ 4,585
Total liabilities	$ 11,377	$ 4,585
Total stockholders' equity	$ 284,568	$ 338,137
Total liabilities and stockholders' equity	**$ 295,945**	**$ 342,722**

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)		*(Audited)*	
Operating expenses:				
Research and development (1)	$ 15,975	$ 6,289	$ 51,100	$ 13,704
General and administrative (2)	5,782	3,842	20,391	7,824
Total operating expenses	21,757	10,131	71,491	21,528
Loss from operations	(21,757)	(10,131)	(71,491)	(21,528)
Other income (expense):				
Interest income	109	-	442	60
Interest expense	-	-	-	(653)
Other income (expense)	10	-	(47)	-
Total other income (expense), net	119	-	395	(593)
Net loss	$ (21,638)	$ (10,131)	$ (71,096)	$ (22,121)
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	-	-	-	(1,869)
Net loss attributable to common stockholders	$ (21,638)	$ (10,131)	$ (71,096)	$ (23,990)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.54)	$ (0.50)	$ (1.80)	$ (3.42)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted (3)	39,742,723	20,155,342	39,524,272	7,021,468

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020

	(Unaudited)		(Unaudited)	
(1) Research and development reconciliation				
GAAP research and development	$ 15,975	$ 6,289	$ 51,100	$ 13,704
Less: share-based compensation expense	2,919	1,475	9,346	1,970
Non-GAAP research and development	$ 13,056	$ 4,814	$ 41,754	$ 11,734
(2) General and administrative reconciliation				
GAAP general and administrative	$ 5,782	$ 3,842	$ 20,391	$ 7,824
Less: share-based compensation expense	1,708	867	6,567	1,108
Non-GAAP general and administrative	$ 4,074	$ 2,975	$ 13,824	$ 6,716

(3) The weighted average shares used to compute net loss attributable to common stockholders include the weighted average effects of the conversion of all outstanding convertible preferred stock into 23,765,065 shares of common stock of the company and the sale of 12,650,000 common shares in connection with the company's November 2020 initial public offering.

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