Erasca Reports Second Quarter 2023 Financial Results and Business Updates

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Significant progress across all clinical programs including Phase 1b combo data for ERAS-007 and ERAS-601, FTD and ODD granted for ERAS-801, and publication of naporafenib combination data

Multiple meaningful clinical catalysts over the next 18 months and beyond

Strong balance sheet with cash, cash equivalents, and marketable securities of $365 million as of June 30, 2023, expected to fund operations into H2 2025

SAN DIEGO, Aug. 10, 2023 (GLOBE NEWSWIRE) -- Erasca, Inc. (Nasdaq: ERAS), a clinical-stage precision oncology company singularly focused on discovering, developing, and commercializing therapies for patients with RAS/MAPK pathway-driven cancers, today reported financial results for the fiscal quarter ended June 30, 2023, and provided business updates.

"Our team continues to achieve important milestones for our four clinical programs that underscore their potential to address unmet needs for multiple patient segments affected by oncogenic RAS/MAPK pathway signaling," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "Expansion of ERAS-007 plus encorafenib and cetuximab (EC) in patients with EC-naïve BRAF-mutated (BRAFm) colorectal cancer (CRC) is advancing following the encouraging early efficacy data seen in HERKULES-3 [50% (3/6) response rate (2 cPR, 1 uPR) at the highest dose tested]. We are also building on the encouraging initial Phase 1b dose escalation data for ERAS-601 plus cetuximab in FLAGSHP-1, with Phase 1b combination dose expansion data planned for the first half of 2024."

Dr. Lim continued, "Importantly, we remain on track to dose the first patient in the SEACRAFT-1 Phase 1b trial in RAS Q61X solid tumors for our most advanced program, the potential first-in-class and best-in-class pan-RAF inhibitor naporafenib. Finally, we are continuing to advance our CNS-penetrant EGFR inhibitor ERAS-801, which was granted FDA Fast Track and Orphan Drug Designations, in recurrent glioblastoma (GBM). Our balance sheet continues to be strong, supporting a cash runway into the second half of 2025 and through the execution of meaningful clinical catalysts over the next 18 months."

Research and Development (R&D) Highlights

- **Presented Promising HERKULES-3 Phase 1b Data and Refined Pipeline:** In June 2023, Erasca presented preliminary Phase 1b data for ERAS-007 in combination with encorafenib + cetuximab (EC) in patients with BRAFm CRC, showing a 50% (3/6) response rate (2 confirmed partial responses, 1 unconfirmed partial response), reinforcing ERAS-007 as a potential best-in-class ERK inhibitor. In addition, a strategic pipeline prioritization sharpened Erasca's focus on existing programs with the highest probability of success.
- **Granted FDA Orphan Drug and Fast Track Designations for ERAS-801:** In June 2023, Erasca announced that the United States Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to ERAS-801 (CNS-penetrant EGFR inhibitor) for the treatment of malignant glioma, which includes GBM. In May 2023, Erasca announced that the FDA granted Fast Track Designation (FTD) to ERAS-801 for the treatment of adult patients with GBM with EGFR gene alterations.
- **Presented Promising FLAGSHP-1 Phase 1b Data:** In April 2023, Erasca presented promising data for ERAS-601 (SHP2 inhibitor) in combination with cetuximab in patients with advanced solid tumors as part of a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting.
- **Announced Publication of Phase 1b Data for Naporafenib:** In April 2023, Erasca announced the publication of results in the *Journal of Clinical Oncology* from the expansion arm of a Phase 1b open label trial evaluating pan-RAF inhibitor naporafenib plus MEK inhibitor trametinib (MEKINIST®) in patients with NRASm melanoma. This potential will be further explored in our SEACRAFT-2 pivotal Phase 3 trial.

Corporate Highlights

- **Appointed Lead Independent Director:** In July 2023, James Bristol, Ph.D., was appointed to the position of lead independent director. In addition to this role, Dr. Bristol shall continue to serve on the board's compensation committee and nominating and corporate governance committee.
- **Strengthened Business Leadership:** In May 2023, Erasca promoted David Chacko, M.D., previously Erasca's chief financial officer, to the dual position of chief financial officer and chief business officer, and Nik Chetwyn, Ph.D., previously Erasca's senior vice president of operations, to chief operating officer.

Key Upcoming Milestones

- **SEACRAFT-1:** Phase 1b trial for naporafenib plus trametinib in patients with RAS Q61X tissue agnostic solid tumors

    - Dosing of the first patient expected in the second half of 2023
    - Initial Phase 1b combination data expected between the second and fourth quarters of 2024
- **SEACRAFT-2:** Randomized pivotal Phase 3 trial for naporafenib plus trametinib in patients with NRASm melanoma
    - Dosing of the first patient expected in the first half of 2024
- **HERKULES-3:** Phase 1b trial for ERAS-007 plus EC in EC-naïve patients with BRAFm CRC
    - Phase 1b combination expansion data in patients with BRAFm CRC expected between the second half of 2023 and the first half of 2024
- **FLAGSHP-1:** Phase 1b trial for ERAS-601 in patients with advanced solid tumors
    - Phase 1b combination expansion data in relevant patient populations, including patients with human papillomavirus (HPV)-negative advanced head and neck squamous cell carcinoma (HNSCC), expected in the first half of 2024
- **THUNDERBBOLT-1:** Phase 1 trial for ERAS-801 in patients with recurrent GBM
    - Initial Phase 1 monotherapy dose escalation data in patients with recurrent GBM expected in the second half of 2023

Second Quarter 2023 Financial Results

Cash Position: Cash, cash equivalents, and marketable securities were $365.3 million as of June 30, 2023, compared to $435.6 million as of December 31, 2022. Erasca expects its current cash, cash equivalents, and marketable securities balance to fund operations into the second half of 2025.

Research and Development (R&D) Expenses: R&D expenses were $26.2 million for the quarter ended June 30, 2023, compared to $27.5 million for the quarter ended June 30, 2022. The decrease was primarily driven by decreases in expenses incurred in connection with clinical trials, preclinical studies, discovery activities and outsourced services and consulting fees, partially offset by increases in facilities-related expenses and depreciation, and personnel costs, including stock-based compensation.

General and Administrative (G&A) Expenses: G&A expenses were $9.8 million for the quarter ended June 30, 2023, compared to $8.4 million for the quarter ended June 30, 2022. The increase was primarily driven by personnel costs, including stock-based compensation expense.

Net Loss: Net loss was $31.8 million, or $(0.21) per basic and diluted share, for the quarter ended June 30, 2023, compared to $35.6 million, or $(0.30) per basic and diluted share, for the quarter ended June 30, 2022.

About Erasca
At Erasca, our name is our mission: To erase cancer. We are a clinical-stage precision oncology company singularly focused on discovering, developing, and commercializing therapies for patients with RAS/MAPK pathway-driven cancers. Our company was co-founded by leading pioneers in precision oncology and RAS targeting to create novel therapies and combination regimens designed to comprehensively shut down the RAS/MAPK pathway for the treatment of cancer. We have assembled what we believe to be the deepest RAS/MAPK pathway-focused pipeline in the industry. We believe our team's capabilities and experience, further guided by our scientific advisory board which includes the world's leading experts in the RAS/MAPK pathway, uniquely position us to achieve our bold mission of erasing cancer.

Cautionary Note Regarding Forward-Looking Statements
Erasca cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: our ability to execute on meaningful catalysts over the next 18 months and beyond for our four clinical programs; our expectations regarding the potential therapeutic benefits and safety profile of our product candidates, including naporafenib, ERAS-007, ERAS-601, and ERAS-801; the planned advancement of our development pipeline, including the anticipated timing of the first patient dosing in the SEACRAFT series of trials, the anticipated timing of data readouts for the SEACRAFT-1, HERKULES-3, FLAGSHP-1, and THUNDERBBOLT-1 trials, and other upcoming development milestones; and our expectation that our current cash, cash equivalents, and marketable securities will fund our operations into the second half of 2025. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: preliminary results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and as more patient data becomes available, including the risk that an unconfirmed partial response to treatment may not ultimately result in a confirmed partial response to treatment after follow-up evaluations; we may not realize the benefits from ERAS-801 receiving FTD and/or ODD from the FDA; our approach to the discovery and development of product candidates based on our singular focus on shutting down the RAS/MAPK pathway, a novel and unproven approach; potential delays in the commencement, enrollment, data readouts, and completion of clinical trials and preclinical studies; our dependence on third parties in connection with manufacturing, research, and preclinical and clinical testing; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval, and/or commercialization, or may result in recalls or product liability claims; unfavorable results from preclinical studies or clinical trials; results from preclinical studies or early clinical trials not necessarily being predictive of future results; we have not conducted any clinical trials of naporafenib and are reliant on data generated by Novartis in prior clinical trials conducted by it; our planned SEACRAFT trials may not support the registration of naporafenib; our assumptions around which programs may have a higher probability of success may not be accurate, and we may expend our limited resources to pursue a particular product candidate and/or indication and fail to capitalize on product candidates or indications with greater development or commercial potential; regulatory developments in the United States and foreign countries; our ability to obtain and maintain intellectual property protection for our product candidates and maintain our rights under intellectual property licenses; the impact of global geopolitical events on our business; our ability to fund our operating plans with our current cash, cash equivalents, and marketable securities; and other risks described in our prior filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our annual report on Form 10-K for the year ending December 31, 2022, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Selected Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2023	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 365,324	$ 435,620
Working capital	300,559	395,806
Total assets	440,662	514,909
Accumulated deficit	(545,951)	(480,971)
Total stockholders' equity	362,705	411,853

Erasca, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 26,218	$ 27,488	$ 53,803	$ 54,917
In-process research and development	—	—	—	2,000
General and administrative	9,752	8,417	19,192	15,493
Total operating expenses	35,970	35,905	72,995	72,410
Loss from operations	(35,970)	(35,905)	(72,995)	(72,410)
Other income (expense)				
Interest income	4,251	388	8,128	502
Other expense	(62)	(91)	(113)	(158)
Total other income (expense), net	4,189	297	8,015	344
Net loss	$ (31,781)	$ (35,608)	$ (64,980)	$ (72,066)
Net loss per share, basic and diluted	$ (0.21)	$ (0.30)	$ (0.43)	$ (0.60)
Weighted-average shares of common stock used in computing net loss per share, basic and diluted	150,037,029	120,193,973	149,772,093	119,844,633
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net	(279)	(272)	248	(1,061)
Comprehensive loss	$ (32,060)	$ (35,880)	$ (64,732)	$ (73,127)

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