Erasca Reports First Quarter 2024 Business Updates and Financial Results

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Median OS of 13-14 months for naporafenib plus trametinib in pooled analysis of patients with NRASm melanoma

Strengthened balance sheet with private placement financing from high-quality new and existing healthcare-focused investors

Pro forma cash, cash equivalents, and marketable securities of $334 million is expected to fund operations into H2 2026

SAN DIEGO, May 08, 2024 (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 provided business updates and reported financial results for the fiscal quarter ended March 31, 2024.

"We started 2024 strong with compelling survival data from a pooled analysis of mature data for naporafenib plus trametinib in patients with NRAS-mutant (NRASm) melanoma, which showed a near doubling of median overall survival (mOS) versus comparable historical controls," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "These data also catalyzed an oversubscribed $45 million financing from new and existing high-quality investors. We are excited about the potential of this combination to improve both progression free survival and overall survival in patients with aggressive melanoma in need of additional treatment options."

Dr. Lim continued, "Throughout the year, we expect several data readouts across our clinical programs, including naporafenib (SEACRAFT-1), ERAS-007 (HERKULES-3), and ERAS-801 (THUNDERBBOLT-1). We also expect to initiate our pivotal SEACRAFT-2 trial evaluating naporafenib in the second quarter, with a randomized readout from Stage 1 of the Phase 3 trial anticipated in 2025. With our recent capital infusion and robust balance sheet, we believe that we have extended our cash runway into the second half of 2026 through multiple key inflection points."

Research and Development (R&D) Highlights

- **Analysis of mOS Data for Naporafenib:** In March 2024, a pooled analysis of patients with NRASm melanoma dosed with the combination of naporafenib and trametinib (MEKINIST®) at two different doses across two different trials (Phase 1b and Phase 2) showed a mOS of 13.0 and 14.1 months, respectively. The pooled dataset at each dose compares favorably relative to historical benchmarks.
- **Hosted an R&D Update Conference Call:** In March 2024, Erasca provided updates on the Company's lead clinical program, naporafenib, and its preclinical ERAS-4 program focused on the development of compounds targeting KRAS-mutant solid tumors.

Corporate Highlights

- **Extended Cash Runway with $45 Million Private Placement Financing:** In March 2024, Erasca entered into an oversubscribed private placement led by high-quality new and existing healthcare-focused investors, which closed in April 2024 (2024 Private Placement), that extended its expected cash runway into the second half of 2026.
- **Entered into Two CTCSAs with Novartis for Naporafenib Combination in SEACRAFT-1 and SEACRAFT-2:** In February 2024, Erasca announced two clinical trial collaboration and supply agreements (CTCSAs) with Novartis pursuant to which Novartis will provide its MEK inhibitor trametinib at no cost to Erasca in connection with two clinical trials evaluating naporafenib in combination with trametinib for the treatment of patients with RAS Q61X solid tumors as part of the ongoing Phase 1b SEACRAFT-1 trial, and for the treatment of patients with previously treated NRASm unresectable or metastatic melanoma as part of the planned randomized pivotal Phase 3 SEACRAFT-2 trial.

Key Upcoming Milestones

- **SEACRAFT-1:** Phase 1b trial for naporafenib (pan-RAF inhibitor) plus trametinib in patients with RAS Q61X tissue agnostic solid tumors
  - 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
  - Phase 3 trial initiation expected in the second quarter of 2024
  - Randomized readout from Stage 1 of the Phase 3 trial expected in 2025
- **HERKULES-3:** Phase 1b trial for ERAS-007 (ERK inhibitor) plus encorafenib (BRAFTOVI®) + cetuximab (ERBITUX®) (EC) in EC-naïve patients with BRAF-mutant (BRAFm) colorectal cancer (CRC)
  - Phase 1b combination data expected in the second quarter of 2024
- **THUNDERBBOLT-1:** Phase 1 trial for ERAS-801 (CNS-penetrant EGFR inhibitor) in patients with EGFR-amplified recurrent glioblastoma (GBM)

- Initial Phase 1 monotherapy data expected in 2024

First Quarter 2024 Financial Results

Cash Position: Cash, cash equivalents, and marketable securities were $297.7 million as of March 31, 2024, compared to $322.0 million as of December 31, 2023. Erasca expects its pro forma cash, cash equivalents, and marketable securities balance of $334 million (inclusive of the net proceeds received from the 2024 Private Placement) to fund operations into the second half of 2026.

Research and Development (R&D) Expenses: R&D expenses were $28.6 million for the quarter ended March 31, 2024, compared to $27.6 million for the quarter ended March 31, 2023. The increase was primarily driven by an increase in expenses incurred in connection with clinical trials, preclinical studies, and discovery activities, partially offset by a decrease in outsourced services and consulting fees.

General and Administrative (G&A) Expenses: G&A expenses were $10.3 million for the quarter ended March 31, 2024, compared to $9.4 million for the quarter ended March 31, 2023. The increase was primarily driven by increases in legal fees and personnel costs, including stock-based compensation expense.

Net Loss: Net loss was $35.0 million, or $(0.23) per basic and diluted share, for the quarter ended March 31, 2024, compared to $33.2 million, or $(0.22) per basic and diluted share, for the quarter ended March 31, 2023.

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 patients with cancer. We have assembled one of 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 expectations regarding the potential therapeutic benefits of our product candidates, including naporafenib, ERAS-007, and ERAS-801; the planned advancement of our development pipeline, including the anticipated timing of data readouts for the SEACRAFT-1 trial, the SEACRAFT-2 trial, the HERKULES-3 trial, and the THUNDERBBOLT-1 trial; the anticipated timing for the initiation of the SEACRAFT-2 trial; our ability to fund our operating plans with our current cash, cash equivalents, and marketable securities into the second half of 2026; and our ability to realize the benefits of the CTCSAs described in this press release. 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: 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; we only have three product candidates in clinical development and all of our other development efforts are in the preclinical or development stage; the analysis of pooled Phase 1 and Phase 2 naporafenib plus trametinib data covers two clinical trials with different designs and inclusion criteria, which cannot be directly compared, and therefore may not be a reliable indicator of mOS data; due to differences between trial designs and subject characteristics, comparing data across different trials may not be a reliable indicator of data; preliminary results of clinical trials 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 more patient data become available; we have not completed 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; potential delays in the commencement, enrollment, 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; the inability to realize any benefits from our current licenses, acquisitions, and collaborations, and any future licenses, acquisitions, or collaborations, and our ability to fulfill our obligations under such arrangements; regulatory developments in the United States and foreign countries; later developments with the FDA or EU health authorities may be inconsistent with the feedback received to date regarding our development plans and trial designs; FTD may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval; 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 ended December 31, 2023, 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.

Erasca, Inc.

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

	March 31, 2024	December 31, 2023
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 297,685	$ 321,992
Working capital	276,380	294,520
Total assets	370,022	395,297
Accumulated deficit	(641,030)	(606,013)

Total stockholders' equity	288,409	316,686

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

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 28,574	$ 27,585
General and administrative	10,277	9,440
Total operating expenses	38,851	37,025
Loss from operations	(38,851)	(37,025)
Other income (expense)		
Interest income	3,900	3,877
Other expense, net	(66)	(51)
Total other income (expense), net	3,834	3,826
Net loss	$ (35,017)	$ (33,199)
Net loss per share, basic and diluted	$ (0.23)	$ (0.22)
Weighted-average shares of common stock used in computing net loss per share, basic and diluted	151,161,741	149,504,216
Other comprehensive income (loss):		
Unrealized (loss) gain on marketable securities, net	(287)	527
Comprehensive loss	$ (35,304)	$ (32,672)

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