

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 28, 2023

Erasca, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40602
(Commission File Number)

83-1217027
(IRS Employer
Identification No.)

3115 Merryfield Row
Suite 300
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 465-6511

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	ERAS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On November 28, 2023, Erasca, Inc. (the Company) announced program updates for its pan-RAF inhibitor naporafenib, and central nervous system (CNS)-penetrant EGFR inhibitor ERAS-801 programs, as well as a strategic program prioritization that extends the Company's projected cash runway from the second half of 2025 to the first half of 2026.

The Company has completed Phase 2 meetings with the U.S. Food and Drug Administration (FDA) and European health authorities on the SEACRAFT-2 Phase 3 trial design that provided clarity on a registrational pathway for naporafenib plus trametinib for patients with NRAS mutant (NRASm) melanoma, including:

- Enrollment of patients with high unmet medical need who progressed on, or are intolerant to, standard of care immune checkpoint inhibitor therapy
- Comparator arm is physicians' choice of cytotoxic chemotherapy or trametinib
- Dual primary endpoint evaluation of progression free survival (PFS) and overall survival (OS), with PFS acceptable for potential initial approval
- The Phase 3 trial consists of two stages: a randomized, controlled, dose optimization stage, for which the Company expects to have a data readout in 2025, and a randomized, controlled stage to support regulatory approval

The anticipated SEACRAFT-2 trial initiation remains on track for the first half of 2024.

Updates with respect to ERAS-801 for patients with recurrent glioblastoma (rGBM) in the Phase 1 THUNDERBOLT-1 trial for the 33 patients enrolled in seven dose escalation cohorts include:

- Maximum tolerated dose (MTD) identified as 240 mg once a day (QD) and MTD-1 identified as 160 mg QD
- ERAS-801 was safe and tolerable at MTD and MTD-1 dose levels. The adverse event profile was consistent with the mechanism of action and observations in non-clinical studies
- ERAS-801 exhibited well behaved pharmacokinetic (PK) characteristics: ERAS-801 showed rapid absorption and had dose-dependent increases in PK exposure. Steady-state PK exposures at doses of 160 mg QD and above exceeded the concentration at which 90% tumor growth inhibition was achieved in the glioblastoma (GBM) patient-derived orthotopic xenograft (PDOX) mouse model.
- Expansion cohorts actively enrolling to collect additional safety, tolerability and preliminary efficacy data to support dose optimization and selection
- Phase 1 dose escalation data is anticipated to be presented at a scientific meeting in the first half of 2024, and expansion cohort data is expected in the second half of 2024

The Company has prioritized the following clinical programs and announced key upcoming milestones, including:

- Naporafenib – Pan-RAF Inhibitor
 - o Dosing of the first patient in pivotal Phase 3 SEACRAFT-2 trial in patients with NRASm melanoma expected in the first half of 2024
 - o Initial signal-seeking Phase 1b efficacy data in relevant tumor types from patients with RAS Q61X solid tumors in ongoing SEACRAFT-1 trial expected between the second and fourth quarters of 2024
- ERAS-801 – CNS-penetrant EGFR Inhibitor
 - o Phase 1 monotherapy dose escalation and expansion data in rGBM expected in 2024
- ERAS-007 – ERK1/2 Inhibitor
 - o Initial dose expansion data from Phase 1b/2 HERKULES-3 trial further evaluating encouraging early efficacy data with ERAS-007 in combination with encorafenib and cetuximab (EC) in EC-naïve patients with BRAF mutant colorectal cancer expected between the second half of 2023 and the first half of 2024

The Company has deprioritized select trials or programs, despite their potential differentiation, to focus the Company's resources on the most promising programs, which is expected to extend the Company's cash runway from the second half of 2025 to the first half of 2026, including:

- FLAGSHIP-1 – Phase 1b combination trial of ERAS-601 SHP2 inhibitor with cetuximab was deprioritized. Though ERAS-601 achieved confirmed responses as a monotherapy and in combination with cetuximab, preliminary data do not justify further development of this combination in FLAGSHIP-1 indications
- ERAS-5 – Preclinical ULK inhibitor
- ERAS-10 – Preclinical protein degrader

The Company's revised program pipeline is set forth on the slide attached as Exhibit 99.1 to this report.

Cautionary Note Regarding Forward-Looking Statements

Erasca cautions you that statements contained in this report 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 the upcoming near-term catalysts for our clinical programs; our expectations regarding the potential therapeutic

benefits and safety profile of our product candidates, including naporafenib, ERAS-007, and ERAS-801; the planned advancement of our development pipeline, including the design of future trials and anticipated timing of the first patient dosing in the SEACRAFT-2 trial, the anticipated timing of data readouts for the SEACRAFT-1, HERKULES-3, and THUNDERBOLT-1 trials, and other upcoming development milestones; our ability to realize the benefits from ERAS-801 receiving Orphan Drug and Fast Track Designations from the FDA; and our expectation that our current cash, cash equivalents, and marketable securities will fund our operations into the first half of 2026. Actual results may differ from those set forth in this report 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; potential delays in the commencement, enrollment, data readouts, and completion of clinical trials and preclinical studies; later developments with the FDA or European health authorities that may be inconsistent with the end of Phase 2 meetings, including that our planned SEACRAFT trials may not support the registration of naporafenib; 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; 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 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 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 and war 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 ended 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.

Item 9.01 Financial Statements and Exhibits.

99.1 [Company Pipeline, dated November 28, 2023](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES







Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Erasca, Inc.

Date: November 28, 2023

By: /s/ Eburn Garner
Eburn Garner, General Counsel

Deep modality-agnostic RAS/MAPK pathway-focused pipeline

Program/Company	Target	Modality	Indication	Discovery	IND-enabling	Phase 1	Phase 2	Phase 3	Erase Cancer Strategy	Worldwide Rights	
Naporafenib	BRAF/CRAF		Pan-RAS Q61X tissue agnostic	SEACRAFT-1						1	ERASCA
			NRASm melanoma	SEACRAFT-2 (planned)						1	ERASCA
			NF1 LOF, pan-RAS G13R, BRAF Class 2/3 solid tumors	SEACRAFT-3 (planned)						1	ERASCA
ERAS-007	ERK1/2		BRAF V600E CRC	HERKULES-3					1	ERASCA	
ERAS-801	EGFR		EGFR-altered GBM	THUNDERBBOLT-1					1	ERASCA	
ERAS-4	Pan-KRAS		KRASm solid tumors						2	ERASCA	
ERAS-12	EGFR D2/D3		EGFR & RAS/MAPK altered tumors						1	ERASCA	
Affini-T	KRAS G12V/D		KRASm solid tumors						2	affini	

 small molecule
  large molecule
  TCR T cell therapy
  ERASCA investment

ERASCA

