

**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): April 1, 2024

Gritstone bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38663
(Commission
File Number)

47-4859534
(IRS Employer
Identification No.)

5959 Horton Street, Suite 300
Emeryville, California
(Address of Principal Executive Offices)

94608
(Zip Code)

Registrant's Telephone Number, Including Area Code: 510 871-6100

(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	GRTS	The Nasdaq Stock Market LLC

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 April 1, 2024, Gritstone bio, Inc. (the “Company”) announced preliminary progression-free survival (“PFS”), long-term circulating tumor DNA (“ctDNA”) and tolerability data from the Phase 2 portion of its randomized, open-label Phase 2/3 study evaluating its personalized cancer vaccine, GRANITE (GRTC901/GRT-R902), in combination with immune checkpoint blockade for patients with front-line metastatic microsatellite stable colorectal cancer. Of the 104 patients randomized, 67 (39 GRANITE arm, 28 control arm) were included in the preliminary dataset, with cutoff dates of March 8, 2024 and March 12, 2024, as indicated below. Thirty-six patients left the study prior to randomized treatment primarily due to early progressive disease or withdrawal of consent, and one patient has yet to begin study treatment start. Demographics and clinical characteristics were balanced between arms (stage, sidedness, presence of liver metastases), with approximately 75% of patients having liver metastases.

Progression-free survival data

Preliminary PFS data showed an overall trend of clinically meaningful improvement in GRANITE recipients, with hazard ratios of 0.82 in all patients ([95% CI, 0.34, 1.67]; 62% censored) and 0.52 (equating to a 48% relative risk reduction of progression or death with GRANITE vs. control) in a high-risk group ([95% CI, 0.15-1.38]; 44% censored); the high risk group defined as baseline ctDNA above the median value (2%) for the control group (ctDNA quantified as mean variant allele frequency (VAF) at the time of study randomization). As of the March 8, 2024 data cut, median PFS in the group of high-risk patients, who typically progress earlier than non-high-risk patients, was 12 months (GRANITE arm) and seven months (control arm). Greater than 90% of patients in the group of high-risk patients had liver metastases.

ctDNA data

As of the March 12, 2024 data cut, preliminary findings of short-term molecular response (>30% reduction in ctDNA using single time-point analysis, defined per protocol) appeared uninformative due to an unanticipated continuation of ctDNA drop beyond induction chemotherapy, and resulted in similar short-term molecular response rates across arms (GRANITE and control). Conversely, long-term ctDNA data demonstrated the expected correlation of ctDNA with clinical benefit and favored GRANITE patients. Multiple subgroup analyses spanning high and low-risk groups demonstrated alignment between ctDNA response and PFS trends.

Tolerability data

GRANITE was generally well tolerated. Common adverse events (“AEs”) were mild systemic and local effects typically associated with any potent vaccine, i.e., transient flu-like illness and the vast majority of AEs were Grade 1/2. As of the March 8, 2024 data cut, no patients had discontinued trial due to an AE.

The Company expects to provide mature PFS data in the third quarter of 2024 and overall survival data in the first half of 2025.

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 thereunto duly authorized.

Gritstone bio, Inc.

Date: April 1, 2024

By: /s/ Andrew Allen
Andrew Allen
President and Chief Executive Officer