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): September 30, 2024

Gritstone bio, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38663**	**47-4859534**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5959 Horton Street, Suite 300 **Emeryville, California**	**94608**
(Address of Principal Executive Offices)	**(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 September 30, 2024, Gritstone bio, Inc. (the "Company") announced interim 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 ("MSS-CRC").

Key Findings from Interim Phase 2 Data in MSS-CRC

Data cut as of August 19, 2024

104 patients were randomized 1:1 in the study: 69 patients (39 GRANITE arm, 30 control arm) are included in the treated analysis below. Demographics and clinical characteristics were balanced between arms (stage, sidedness, presence of liver metastases), with the vast majority (80%) of patients having liver metastases in the treated analysis. Thirty-five patients did not advance to study treatment after oxaliplatin, most commonly due to withdrawing consent (n=15), disease progression (n=8), and other reasons (n=12) (12 in GRANITE arm; 23 in control arm).

- Interim data demonstrated an emerging progression-free survival ("PFS") benefit to all GRANITE recipients (study not statistically powered for PFS)
    - 21% relative risk reduction of progression or death with GRANITE vs. standard of care ("SOC") control in all treated population (HR=0.79 [95% CI, 0.42-1.s])
    - 33% (13/39) GRANITE and 23% (7/30) of control patients remain on study and free of progression
        - Last circulating tumor DNA ("ctDNA") assessment is below the assay limit of quantitation in 12/13 GRANITE and 4/7 control patients
- Clinical benefit was most notable in patients with low disease burden (defined as patients with ctDNA equal to or below the trial population median value at study entry)
    - 38% relative risk reduction of progression or death with GRANITE vs. SOC control with low ctDNA subgroup (HR=0.62 [95% CI, 0.23-1.70])
    - Low baseline ctDNA is a likely prognostic and predictive factor
- Immune data were consistent with clinical activity
    - Functional neoantigen-specific T cells were observed in all 16/16 GRANITE patients tested by ELISPOT
    - Association of PFS and peak ex vivo ELISPOT responses was apparent, suggesting that ex vivo ELISPOT may be a surrogate for PFS
- GRANITE demonstrated a favorable safety and tolerability profile
    - No patients discontinued study treatment due to an adverse event ("AE")
    - Common AEs were the mild systemic and local effects associated with any potent vaccine, i.e. transient flu-like illness
    - One treatment-related serious AE (fatigue) occurred in the GRANITE arm (patient continued GRANITE treatment without recurrence upon recovery)

The Company plans to review the PFS data with the U.S. Food and Drug Administration in the coming months and agree on next steps to advance GRANITE, including a potential Phase 2 or 3 trial using ctDNA levels as eligibility criteria.

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: September 30, 2024

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