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): February 12, 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	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 2.02 Results of Operations and Financial Condition.

Gritstone bio, Inc. (the "**Company**") estimates that its cash, cash equivalents, marketable securities and restricted cash as of December 31, 2023 was approximately $86.9 million, inclusive of estimated contribution revenue of approximately $9.0 million for the year ended December 31, 2023, from the Company's contract with the Biomedical Advanced Research and Development Authority ("**BARDA**"), a component of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services, dated September 27, 2023 (as amended, the "**BARDA Contract**"). The Company's actual consolidated cash, cash equivalents, marketable securities and restricted cash balance and its contribution revenue from BARDA under the BARDA Contract as of December 31, 2023 are preliminary, unaudited and may differ from these estimates due to the completion of the Company's year-end closing and auditing procedures. These results were prepared by management and were based on the most current information available to management, and are subject to completion by management of the financial statements as of and for the year ended December 31, 2023, including performance of the Company's financial closing procedures, any final adjustments and other developments that may arise between now and the time the financial results for this period are finalized, and the completion of the external audit of such financial statements. The Company's independent registered public accounting firm has not audited, reviewed, compiled, or applied agreed-upon procedures with respect to the preliminary financial data included herein. Accordingly, the Company's independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto.

Based on the Company's current business plans and assumptions, including its updated timeline for the Company's Phase 2b clinical trial of its next-generation self-amplifying mRNA vaccine candidate against COVID-19, GRT-R924 (the "**Phase 2b Trial**") and changes in estimates to related BARDA reimbursements, the Company estimates its cash runway will be sufficient to fund the Company's operations into the third quarter of 2024.

The information in this Item 2.02, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("**Exchange Act**"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On February 12, 2024, the Company announced its decision to postpone the Phase 2b Trial until the fall of 2024 rather than the first quarter of 2024. The Company made this decision following communications with the U.S. Food and Drug Administration (the "**FDA**") with respect to the Company's investigational new drug application relating to the Company's next generation COVID-19 vaccine candidate, GRT-R924, intended to be tested in the Phase 2b Trial. The FDA informed the Company that, with respect to the Phase 2b Trial, the Company would be required to use fully GMP-grade materials, as well as implement certain other minor changes. The Company's other programs are not affected by this development.

Forward Looking Statements

This current report contains forward-looking statements, including, but not limited to, statements related to the Company's clinical and regulatory development plans for the Company's next-generation COVID-19 vaccine, the timing of commencement of the Phase 2b Trial; the Company's expectations regarding the data to be derived in its ongoing and planned clinical trials; and the Company's ability to discover, develop, manufacture and advance its product candidates, including, in particular, the next-generation self-amplifying mRNA vaccine candidate against COVID-19 into, and successfully complete, clinical trials. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including the Company's programs' clinical stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, the Company's ability to successfully establish, protect and defend its intellectual property and other matters that could affect the sufficiency of existing cash to fund operations. The Company undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see the Company's most recent Annual Report on Form 10-K filed on March 9, 2023 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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: February 12, 2024

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