
**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): March 05, 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 2.02 Results of Operations and Financial Condition.

On March 5, 2024, Gritstone bio, Inc. issued a press release announcing its financial results for the year ended December 31, 2023 and provided a business update. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated March 5, 2024.
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 thereunto duly authorized.

Gritstone bio, Inc.

Date: March 5, 2024

By: /s/ Andrew Allen

Andrew Allen

President and Chief Executive Officer

Gritstone bio Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Updates

- Preliminary data from Phase 2 portion of Phase 2/3 study evaluating GRANITE, Gritstone's personalized cancer vaccine in front-line metastatic, microsatellite-stable colorectal cancer (MSS-CRC) remain expected in 1Q 2024 --
- National Cancer Institute-led Phase 1 study evaluating Gritstone's "off-the-shelf" cancer vaccine, SLATE, combined with neoantigen cell therapy expected to begin in the coming months --
- Gritstone incorporating GMP-grade raw materials in the manufacture of its samRNA vaccine for COVID-19, preparing to launch Phase 2b head-to-head study in the Fall of 2024 --
- Cash, cash equivalents, marketable securities and restricted cash of \$86.9 million as of December 31, 2023 --

EMERYVILLE, CALIF. – March 5, 2024 (GLOBE NEWSWIRE) – Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today reported financial results for the fourth quarter and full year ended December 31, 2023 and provided recent corporate and clinical updates.

"As we rapidly approach the first randomized dataset from our flagship oncology program, GRANITE, we remain focused on leveraging our innovative technologies to drive transformative advances in oncology and infectious disease," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "The continued collaboration with Dr. Rosenberg and the National Cancer Institute involving our 'off-the-shelf' oncology vaccine highlights the pioneering vision and scientific rigor upon which we have built the SLATE and GRANITE platforms. And the recent decision to incorporate GMP-grade materials in the manufacture of our self-amplifying mRNA (samRNA) candidate enhances the potential regulatory utility of the Phase 2b CORAL-BARDA study, as well as our broader platform, an important development as we prepare to launch the study later this year."

Dr. Allen added, "Preliminary Phase 2 data from the Phase 2/3 study of GRANITE in metastatic MSS-CRC are rapidly accruing and remain expected this quarter. Positive signal in this metastatic context would likely unlock enormous opportunity in both adjuvant and metastatic solid tumors. As the calendar flips further into 2024, Gritstone continues marching forward toward potentially enabling the full potential of our novel vaccine platforms in both oncology and infectious disease."

Corporate Update

- In February 2024, Gritstone bio reduced its workforce by approximately 40% to reduce costs and preserve capital. The reduction primarily impacted employees associated with vaccine manufacturing and clinical infectious disease operations, who were not active in the ongoing Phase 2 study of GRANITE, Gritstone's personalized cancer vaccine. The reduction occurred approximately two weeks following the previously announced delay of the proposed CORAL Phase 2b study, which resulted in Gritstone not receiving external funding it previously anticipated beginning in 1Q 2024, associated with the initiation of the study.
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Clinical Program Updates

Tumor-Specific Neoantigen Oncology Programs (GRANITE and SLATE)

GRANITE – Personalized neoantigen vaccine program

SLATE – “Off-the-shelf” neoantigen vaccine program

- **The Phase 2 portion of the Phase 2/3 study evaluating GRANITE as a front-line maintenance therapy in metastatic MSS-CRC remains ongoing and preliminary efficacy data from the Phase 2 portion remain expected in the first quarter of 2024.** Gritstone met its enrollment target of 100 patients randomized in August 2023.
- **The clinical trial collaboration with the National Cancer Institute (NCI) to evaluate an autologous mutant KRAS-directed TCR-T cell therapy in combination with Gritstone’s KRAS-directed “off the shelf” vaccine candidate, SLATE-KRAS, is ongoing.** The study is led by Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI's Center for Cancer Research and builds into the growing interest in combining tumor-antigen specific cell therapy with matched vaccines. The IND was cleared by the U.S. Food and Drug Administration (FDA) in October 2023.
- **Pending funding, Gritstone remains ready to initiate a randomized Phase 2 clinical trial within SLATE (“off-the-shelf” neoantigen vaccine program).**

Infectious Disease Programs

CORAL – Next-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone’s samRNA platform and novel approach in infectious diseases

- **In February 2024, Gritstone announced it will incorporate GMP-grade materials in the manufacture of its self-amplifying mRNA (samRNA) candidate, resulting in a delay of the CORAL Phase 2b study (CORAL-BARDA).** The move is expected to increase the regulatory utility of the anticipated 10,000 subject, comparative Phase 2b study contracted by the Biomedical Advanced Research and Development Authority (BARDA)^(a). Gritstone is now preparing to launch the study in Fall 2024.

HIV – Collaboration with Gilead under Gilead’s HIV Cure Program to research and develop vaccine-based HIV immunotherapy treatment

- **The collaboration with Gilead to research and develop a vaccine-based HIV immunotherapy treatment continues under Gilead’s direction.**

Full Year 2023 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were \$86.9 million as of December 31, 2023, compared to \$185.2 million as of December 31, 2022.
 - **Research and development expenses** were \$127.2 million for the year ended December 31, 2023 compared to \$111.4 million for the year ended December 31, 2022. The increase was primarily due to increases in personnel-related costs and clinical trial expenses.
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- **General and administrative expenses** were \$28.8 million for the year ended December 31, 2023 compared to \$29.0 million for the year ended December 31, 2022. The decrease was primarily attributable to a decrease in outside services for legal, finance, recruiting and other professional services to support our ongoing operations due to the recruitment of full-time equivalents, offset by an increase in personnel-related and facility related costs.
- **Collaboration, license, and grant revenues** were \$16.3 million for the year ended December 31, 2023 compared to \$19.9 million for the year ended December 31, 2022. During the year ended December 31, 2023, we recorded \$9.0 million of grant revenue from the BARDA Contract, \$4.3 million of grant revenue related to the CEPI Agreement and \$1.7 million in grant revenue related to the Gates Agreement. During the year ended December 31, 2023, we recorded \$1.0 million in collaboration revenue related to the 2seventy Agreement and \$0.3 million in collaboration revenue related to the Gilead Collaboration Agreement.

^(a) This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00062.

About Gritstone bio

Gritstone bio, Inc. (Nasdaq: GRTS) is a clinical-stage biotechnology company that aims to develop the world's most potent vaccines. We leverage our innovative vectors and payloads to train multiple arms of the immune system to attack critical disease targets. Independently and with our collaborators, we are advancing a portfolio of product candidates to treat and prevent viral diseases and solid tumors in pursuit of improving patient outcomes and eliminating disease. www.gritstonebio.com

Gritstone Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to our clinical and regulatory development plans for our product candidates; our expectations regarding the data to be derived in our ongoing and planned clinical trials; the timing of commencement of our future nonclinical studies, clinical trials and research and development programs; our ability to discover, develop and advance product candidates into, and successfully complete, clinical trials; and our plans and strategy regarding maintaining existing and entering into new collaborations and/or partnerships. Such forward-looking statements involve substantial risks and uncertainties that could cause Gritstone'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 Gritstone'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, Gritstone'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. Gritstone 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 Gritstone's most recent Annual Report on Form 10-K filed on March 5, 2024 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

Gritstone Contacts

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Gritstone bio, Inc.
Consolidated Balance Sheets
(In thousands)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,986	\$ 55,498
Marketable securities	16,288	116,389
Restricted cash	2,299	3,977
Prepaid expenses and other current assets	5,862	7,014
Total current assets	87,435	182,878
Long-term restricted cash	5,290	5,290
Property and equipment, net	17,281	21,335
Lease right-of-use assets	66,839	17,481
Deposits and other long-term assets	924	9,739
Long-term marketable securities	—	4,031
Total assets	\$ 177,769	\$ 240,754
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,819	\$ 8,694
Accrued compensation	9,357	8,215
Accrued liabilities	1,213	4,124
Accrued research and development expenses	3,696	3,343
Lease liabilities, current portion	6,904	5,294
Deferred revenue, current portion	2,350	5,131
Total current liabilities	27,339	34,801
Other liabilities, noncurrent	709	150
Lease liabilities, net of current portion	57,727	15,673
Debt, noncurrent	40,144	19,349
Total liabilities	125,919	69,973
Stockholders' equity:		
Common stock	22	22
Additional paid-in capital	711,386	691,910
Accumulated other comprehensive gain (loss)	3	(80)
Accumulated deficit	(659,561)	(521,071)
Total stockholders' equity	51,850	170,781
Total liabilities and stockholders' equity	\$ 177,769	\$ 240,754

Gritstone bio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Revenues:		
Collaboration and license revenues	\$ 1,331	\$ 9,269
Grant revenues	15,013	10,676
Total revenues	16,344	19,945
Operating expenses:		
Research and development	127,182	111,403
General and administrative	28,783	28,970
Total operating expenses	155,965	140,373
Loss from operations	(139,621)	(120,428)
Interest income	5,199	1,976
Interest expense	(4,036)	(1,235)
Other expense	(32)	—
Net loss	(138,490)	(119,687)
Other comprehensive loss:		
Unrealized gain (loss) on marketable securities	83	(7)
Comprehensive loss	\$ (138,407)	\$ (119,694)
Net loss per share, basic and diluted	\$ (1.20)	\$ (1.32)
Weighted-average number of shares used in computing net loss per share, basic and diluted	115,527,546	90,918,333

