

**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): August 09, 2023

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	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.

On August 9, 2023, Gritstone bio, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 9, 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 thereunto duly authorized.

Gritstone bio, Inc.

Date: August 9, 2023

By: /s/ Andrew Allen

Andrew Allen
President and Chief Executive Officer

Gritstone bio Reports Second Quarter 2023 Financial Results and Provides Corporate Updates

-- Enrollment completed in Phase 2 portion of Phase 2/3 study evaluating GRANITE (personalized cancer vaccine [PCV]) in first-line metastatic microsatellite-stable colorectal cancer (MSS-CRC); preliminary efficacy data expected in 1Q 2024 --

-- Gritstone partnering with Friends of Cancer Research (Friends) on Friends' ctDNA for Monitoring Treatment Response (ctMoniTR) Project, a collaborative research initiative to inform use of ctDNA change as surrogate for survival benefit --

-- Publication in Nature Communications of interim CORAL-BOOST results highlights the potential of Gritstone's self-amplifying mRNA (samRNA) candidates to serve as next-generation vaccine against SARS-CoV-2 --

-- Cash, cash equivalents, marketable securities, and restricted cash of \$122.3 million as of June 30, 2023 --

EMERYVILLE, CALIF. – August 9, 2023 (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 second quarter ended June 30, 2023 and provided recent corporate and clinical updates.

"We are pleased with the pace at which our randomized GRANITE Phase 2/3 trial is advancing. Completing enrollment for the Phase 2 portion underscores the enthusiasm for this trial, related to the high unmet need for better treatments in common, immunologically cold tumors, such as CRC," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "Our partnership with Friends of Cancer Research on ctMoniTR, a project to collate data across the industry to validate the use of circulating tumor DNA (ctDNA) as an early predictor of treatment outcomes, will help further define the emerging potential of ctDNA as a superior method over radiology-based approaches to evaluate early treatment effects of immunotherapy. Molecular response, or reduction in ctDNA, is the primary efficacy endpoint for the Phase 2 portion of the GRANITE trial. GRANITE has the potential to be the first neoantigen-based PCV to demonstrate efficacy in a randomized study against a cold tumor, which would be a transformational advance for the field. We look forward to sharing preliminary Phase 2 efficacy data in frontline MSS-CRC in the first quarter of 2024."

Dr. Allen continued, "Additionally, the promising data we continue to see from our CORAL (SARS-CoV-2 vaccine) program highlights the differentiation and potential advantages of self-amplifying mRNA (samRNA) over current vaccines against infectious diseases. Our recent publication in Nature Communications demonstrates the scientific rigor of our work to date and the ability of our samRNA platform to drive potent and durable immune responses. We believe our samRNA vaccine candidates have demonstrated strong potential to serve as next-generation vaccine solutions to COVID-19 and other infectious diseases."

Corporate Update

- **In August 2023, Gritstone announced it is partnering with the Friends of Cancer Research (Friends) in support of its ctDNA for Monitoring Treatment Response (ctMoniTR) Project.** The ctMoniTR Project is a collaboration between industry, academia and government to provide data to inform the application and adoption of circulating tumor DNA (ctDNA) in drug development. Per the agreement, Gritstone will be providing data to help inform the use of change in ctDNA as an early indicator of long-term clinical benefit in cancer patients.
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Clinical Program Updates

Tumor-Specific Neoantigen Oncology Programs

GRANITE - Individualized neoantigen vaccine against cold tumors

SLATE - "Off-the-shelf" neoantigen vaccine program

- **Enrollment is now complete in the Phase 2 portion of the Phase 2/3 study, which is evaluating GRANITE as a maintenance therapy in first-line metastatic microsatellite-stable colorectal cancer (MSS-CRC).** The company has met its target of 100 patients randomized. Preliminary efficacy data on approximately 50 patients who have completed at least 4 months of maintenance treatment is expected in the first quarter of 2024.
- **Gritstone delivered multiple presentations detailing advances in neoantigen prediction capabilities and cancer vaccine programs at the 2023 American Association for Cancer Research (AACR 2023, in April 2023).**
 - o GRANITE (individualized neoantigen program) presentation: Longitudinal analysis of participants in the GRANITE Phase 1/2 supports vaccine-elicited priming and boosting of antigen-specific T cell populations associated with conversion of "cold" to "hot" tumors and molecular responses.
 - o EDGE™ (Epitope Discovery for Genomes Platform) poster: Advances in EDGE™ models (Gritstone's AI-driven neoantigen prediction platform) enable potential best-in-class prediction of class II HLA-presented neoantigens that could drive CD4+ T cell responses.
 - o SLATE ("off-the-shelf" neoantigen vaccine program) poster: Description of a novel KRAS G12C class II epitope with evidence of clinical benefit associated with vaccine-elicited T cell response.
- **The clinical trial collaboration with the National Cancer Institute (NCI) to evaluate an autologous T cell therapy in combination with Gritstone's KRAS-directed vaccine candidate, SLATE-KRAS, is ongoing.** Under the terms of the collaboration, Gritstone will provide the SLATE-KRAS vaccine as requested by NCI. NCI will be responsible for conducting the study.
- **Gritstone expects to initiate a randomized Phase 2 clinical trial within SLATE ("off-the-shelf" neoantigen vaccine program) in 2024.**

Infectious Disease Programs

CORAL – Second-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's infectious disease approach and the potential application of samRNA in infectious diseases.

- **In June 2023, interim results from the ongoing CORAL-BOOST study (Phase 1 study evaluating the company's self-amplifying mRNA (samRNA) vaccine as a boost against COVID-19) were published in Nature Communications.** The results demonstrate that Gritstone's samRNA vaccine candidate boosted immunity for at least 6 months in previously vaccinated older adults and support our initial findings from a separate Phase 1 study in previously unvaccinated subjects (CORAL-CEPI).
 - **In April 2023, Gritstone presented new data from two ongoing Phase 1 studies demonstrating persistence of high neutralizing antibodies for at least 6 months following samRNA vaccine across multiple settings and**
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subject populations. Both datasets were presented at the 33rd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2023).

- o **CORAL-CEPI poster:** Results from Part A of the CORAL-CEPI study (total study n = 342), primary series samRNA vaccination shown to elicit strong neutralizing antibody (nAb) responses that persist for at least 6 months, including variant cross-reactive nAb, in previously unvaccinated ("vaccine-naïve") South African subjects. Enrollment in CORAL-CEPI completed in February 2023.
- o **CORAL-BOOST poster:** Results from cohorts 3 and 4 of the CORAL-BOOST study showed the samRNA elicited robust nAbs, and that these nAbs persisted for at least 6 months regardless of primary series (adenovirus or mRNA). These results are generally consistent with 6-month neutralizing antibody results from cohorts 1 and 2 of the study, which evaluated samRNA as a boost following Vaxzevria (adenovirus) only ([August 2022](#)).
- **Enrollment in the CORAL-NIH trial completed in 2022.** This study is sponsored and executed by NIAID.
- **Gritstone expects to share additional data from the CORAL-CEPI and CORAL-BOOST studies in Fall 2023.**

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 remains active and ongoing.**

Second Quarter 2023 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were \$122.3 million as of June 30, 2023, compared to \$185.2 million as of December 31, 2022.
 - **Research and development expenses** were \$31.0 million for the three months ended June 30, 2023, compared to \$27.3 million for the three months ended June 30, 2022. The increase of \$3.6 million was primarily due to increases of \$1.0 million in personnel-related expenses, \$1.0 million in laboratory supplies, and \$2.5 million in facilities-related costs, offset by decreases of \$0.8 million in outside services, consisting primarily of clinical trial and other chemistry, manufacturing and controls ("CMC") related expenses and \$0.1 million in milestone and license payments.
 - **General and administrative expenses** were \$6.7 million for the three months ended June 30, 2023, compared to \$7.8 million for the three months ended June 30, 2022. The decrease of \$1.1 million was primarily due to decreases of \$1.3 million in outside services and \$0.1 million in personnel-related expenses, offset by an increase of \$0.3 million in facilities-related costs.
 - **Collaboration, license, and grant revenues** were \$2.0 million for the three months ended June 30, 2023, compared to \$5.5 million for the three months ended June 30, 2022. During the three months ended June 30, 2023, we recorded \$0.1 million in collaboration revenue related to the Gilead Collaboration Agreement, \$0.3 million in collaboration revenue related to the 2seventy Agreement, \$1.1 million in grant revenue from the CEPI Funding Agreement, and \$0.5 million in grant revenue from the Gates Foundation.
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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 and have programs in viral diseases and solid tumors. Independently and with our partners, we are advancing a portfolio of product candidates with the aim 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 9, 2023 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

Gritstone Contacts

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 41,414	\$ 55,498
Marketable securities	73,119	116,389
Restricted cash	2,437	3,977
Prepaid expenses and other current assets	5,406	7,014
Total current assets	122,376	182,878
Long-term restricted cash	5,290	5,290
Property and equipment, net	20,443	21,335
Lease right-of-use assets	71,985	17,481
Deposits and other long-term assets	2,529	9,739
Long-term marketable securities	—	4,031
Total assets	\$ 222,623	\$ 240,754
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,925	\$ 8,694
Accrued compensation	6,036	8,215
Accrued liabilities	1,452	4,124
Accrued research and development expenses	2,042	3,343
Lease liabilities, current portion	4,838	5,294
Deferred revenue, current portion	2,818	5,131
Total current liabilities	22,111	34,801
Other liabilities, noncurrent	398	150
Lease liabilities, net of current portion	60,824	15,673
Debt, noncurrent	29,723	19,349
Total liabilities	113,056	69,973
Stockholders' equity:		
Preferred stock	—	—
Common stock	22	22
Additional paid-in capital	699,979	691,910
Accumulated other comprehensive loss	(125)	(80)
Accumulated deficit	(590,309)	(521,071)
Total stockholders' equity	109,567	170,781
Total liabilities and stockholders' equity	\$ 222,623	\$ 240,754

Gritstone bio, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration and license revenues	\$ 400	\$ 2,761	\$ 941	\$ 7,506
Grant revenues	1,555	2,710	3,456	5,156
Total revenues	1,955	5,471	4,397	12,662
Operating expenses:				
Research and development	30,967	27,347	61,481	55,546
General and administrative	6,716	7,792	13,461	15,747
Total operating expenses	37,683	35,139	74,942	71,293
Loss from operations	(35,728)	(29,668)	(70,545)	(58,631)
Interest income	1,479	153	3,157	200
Interest expense	(985)	—	(1,828)	—
Other expense	(22)	—	(22)	—
Net loss	(35,256)	(29,515)	(69,238)	(58,431)
Other comprehensive loss:				
Unrealized loss on marketable securities	(73)	(19)	(45)	(337)
Comprehensive loss	\$ (35,329)	\$ (29,534)	\$ (69,283)	\$ (58,768)
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.34)	\$ (0.60)	\$ (0.68)
Weighted-average number of shares used in computing net loss per share, basic and diluted				
	114,929,523	86,448,632	114,676,261	86,363,116

