

**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 04, 2022**

**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:**

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 4, 2022, Gritstone bio, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2022 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release dated August 4, 2022.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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 4, 2022

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

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## Gritstone Reports Second Quarter 2022 Financial Results and Provides Business Update

-- Clinical programs continue to progress, with initial data from Phase 2 study of “off the shelf” SLATE-KRAS and multiple studies within T cell-enhanced SARS-CoV-2 program (CORAL) expected this year --

-- Follow up data from subset of CORAL-BOOST study shows strong neutralizing antibody titers persisted without decay for at least 6 months after single boost administration of self-amplifying mRNA (samRNA) --

-- New credit facility provides financial flexibility entering period of multiple potential milestones --

-- Cash, cash equivalents, marketable securities and restricted cash of \$159.2 million as of June 30, 2022 --

-- Gritstone will host a conference call today, August 4 at 4:30 p.m. ET --

**EMERYVILLE, CALIF.** – August 04, 2022 (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, 2022 and reviewed business highlights.

“With steady execution of multiple clinical programs around the world, we are building momentum for the many datasets expected from SLATE, CORAL and GRANITE over the coming months and through 2023,” said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. “We have observed a correlation between molecular response and extended overall survival in multiple subjects with end-stage colorectal cancer treated with GRANITE, our individualized neoantigen immunotherapy. Today, we shared data demonstrating that the high neutralizing antibody titers to SARS-CoV-2 induced by our self-amplifying mRNA (samRNA) vaccine candidate persisted with no decay for at least 6 months. These data, from a subset of subjects in our CORAL-BOOST study, are encouraging since lack of neutralizing antibody persistence is a major limitation of first-generation vaccines, necessitating frequent boost vaccinations. Our novel samRNA vaccine platform may be driving this durable effect due to its self-replicating nature, an inherent potential benefit of samRNA compared to first-generation mRNA vaccines. We look forward to sharing more data from the CORAL (SARS-CoV-2) program, as well as the SLATE programs later this year.”

### Clinical Program Updates

#### Tumor-Specific Neoantigen (TSNA) Oncology Programs

*GRANITE – Individualized, TSNA-directed vaccine-based immunotherapy*

- In May, Gritstone provided updated overall survival (OS) data from GRANITE Phase 1/2 study in end-stage colorectal cancer (n=9).
    - o Of the four patients who demonstrated molecular response, median overall survival (mOS) is not yet reached and will exceed 18 months. This compares to 7.8 months mOS in those who did not have a molecular response.
    - o All patients alive at the time of the ESMO 2021 data presentation (the initial presentation of data from the Phase 1/2 study) remain alive after an additional 35 weeks of follow-up.
  - GRANITE-CRC-1L, a randomized, controlled Phase 2/3 trial evaluating GRANITE in combination with immune checkpoint blockade for frontline maintenance treatment of newly diagnosed patients with metastatic, microsatellite-stable colorectal cancer (MSS-CRC), is ongoing. Preliminary data (molecular response and progression-free survival) from the Phase 2 portion of the trial are expected in 2H 2023.
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- GRANITE-ADJUVANT, a randomized, controlled Phase 2 trial in patients with high-risk stage II/III colon cancer who are circulating tumor DNA (ctDNA)+ after definitive surgery, is open for enrollment.

*SLATE – “Off-the-shelf” shared neoantigen-directed vaccine-based immunotherapy intended for patients who have relevant KRAS mutations and suitable tissue type (HLA)*

- Initial data from the ongoing Phase 2 study of SLATE-KRAS, an optimized, KRAS-specific version of SLATE, will be presented during a mini-oral presentation at the European Society for Medical Oncology (ESMO) in September 2022. SLATE-KRAS is being evaluated in patients with advanced non-small cell lung cancer (NSCLC) and CRC.
  - o Early signals from the ongoing Phase 2 study support the potential of SLATE-KRAS to drive stronger CD8+ T cell responses to mutant KRAS than Gritstone’s original candidate, SLATE v1.
- Gritstone intends to continue advancing its existing candidate, SLATE-KRAS, and has a long-term objective of developing a suite of “off-the-shelf” product candidates that target highly prevalent tumor-specific antigens across a number of patient populations and cancer types.

### **Infectious Disease Programs**

Gritstone’s infectious disease programs aim to deliver vaccine candidates that drive both B cell and T cell immunity with the potential to provide either a protective or therapeutic effect across a broad array of viral diseases.

*CORAL – Second-generation SARS-CoV-2 vaccine program delivering both Spike and highly conserved non-Spike T cell epitopes (TCEs) with a focus on the samRNA vector. This approach offers potential for more durable clinical protection and broader immunity against SARS-CoV-2 variants than first generation mRNA products by inducing potent and persistent neutralizing antibody responses with broad variant protection, plus T cell responses to conserved regions from across the SARS-CoV-2 genome (not just Spike).*

- In June, results from a preclinical study of its samRNA vaccine against SARS-CoV-2 were published in Nature Communications (article [here](#)). The results of the study, which were previously pre-printed in bioRxiv (in November 2021), demonstrate the samRNA vaccine candidate induced broad and potent neutralizing antibodies and T cell immune responses following administration to non-human primates (NHP) at low doses, and that these immune responses were protective against SARS-CoV-2 challenge.
  - Today, Gritstone reported antibody durability results from the first two cohorts of its CORAL-BOOST trial showing the strong neutralizing antibody response observed following single boost administration of samRNA (10µg or 30µg) persisted without decay after 6 months. In a small subset of subjects who elected to receive only a single samRNA boost vaccination (n=7), at six months:
    - o Durable neutralizing antibodies against wild type Spike as well as key Spike variants of concern (Beta, Delta and Omicron) were observed.
    - o Neutralizing antibody titers formed a plateau and remained stable for at least 6 months.
    - o These results can be found in [Gritstone’s corporate presentation](#).
    - o Additionally, T cell responses to Spike and non-Spike T cell epitopes (TCEs) remained generally stable over the 6-month observation period (Omicron mutations impacted TCEs minimally).
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- Three Phase 1 studies – CORAL-BOOST, CORAL-CEPI and CORAL-NIH – are ongoing and data from each are expected in the second half of 2022.
  - o The CORAL-BOOST study is a Phase 1 study in the UK evaluating a T cell enhanced samRNA vaccine as a booster against SARS-CoV-2 in healthy volunteers over 60 years old who had received two prior doses of Vaxzevria (AstraZeneca COVID-19 vaccine). In January, Gritstone announced positive clinical data from the first cohort and subsequently expanded the study to permit boosting after both mRNA as well as adenoviral primary vaccine series.
  - o The CORAL-CEPI trial is ongoing in South Africa with support from the Coalition for Epidemic Preparedness Innovations (CEPI) and is evaluating T cell enhanced omicron- and beta-spike (plus TCE) constructs in virus-naïve, convalescent, and HIV+ patients.
  - o The CORAL-NIH trial, which is being sponsored and executed by the National Institute of Allergy and Infectious Disease (NIAID), is ongoing in the United States evaluating T cell enhanced samRNA and/or adenoviral vaccines in previously vaccinated healthy volunteers.

*HIV – Collaboration with Gilead Sciences, Inc. (Gilead) under Gilead's HIV Cure Program to research and develop vaccine-based HIV immunotherapy treatment*

- An investigational new drug application (IND) was cleared in December 2021.
- If Gilead decides to progress development beyond the initial Phase 1 study by exercising their exclusive option, the Company will receive a \$40.0 million non-refundable option exercise fee.

### **Corporate Highlights**

- Established a credit facility of up to \$80 million with Hercules Capital (NYSE: HTGC) and Silicon Valley Bank and drew \$20 million at closing (July 2022). An additional \$10 million is available for drawdown by March 15, 2023, and the remaining \$50 million becomes available in tranches through June 15, 2024, upon achievement of certain milestones by Gritstone. Gritstone is under no obligation to draw funds in the future, and there are no warrants associated with this transaction.
- Earned Great Place to Work® Certification (May 2022).

### **Second Quarter 2022 Financial Results**

**Cash, cash equivalents, marketable securities and restricted cash** were \$159.2 million as of June 30, 2022, compared to \$223.5 million as of December 31, 2021.

**Research and development expenses** were \$27.3 million for the three months ended June 30, 2022, compared to \$22.1 million for the three months ended June 30, 2021. The increase of \$5.2 million was primarily due to increases of \$1.9 million in personnel-related expenses, \$3.1 million in outside services, consisting primarily of clinical trial and other chemistry, manufacturing and controls (“CMC”) related expenses, and \$0.8 million in facilities related costs, offset by a decrease of \$0.5 million in laboratory supplies.

**General and administrative expenses** were \$7.8 million for the three months ended June 30, 2022, compared to \$5.9 million for the three months ended June 30, 2021. The increase of \$1.9 million was primarily attributable to increases of \$1.5 million in personnel-related expenses and \$0.6 million in outside services, offset by a decrease of \$0.2 million in facilities-related costs.

**Collaboration, license, and grant revenues** were \$5.5 million for the three months ended June 30, 2022, compared to \$2.8 million for the three months ended June 30, 2021. The \$2.7 million increase was primarily attributable to revenue recognized under the CEPI Funding Agreement, which was entered into in August 2021, for the three months ended June 30, 2022.

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## **Conference call and webcast details**

A conference call to discuss second quarter results will be held at 4:30 p.m. ET August 4:

Conference call: 800-263-0877

Conference passcode: 8108859

Webcast: [https://event.webcasts.com/starthere.jsp?ei=1561514&tp\\_key=4f6eab0ea9](https://event.webcasts.com/starthere.jsp?ei=1561514&tp_key=4f6eab0ea9)

## **About Gritstone**

Gritstone is working to create 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](http://www.gritstonebio.com)

## **Gritstone Forward-Looking Statements**

This press release contains forward-looking statements, including, but not limited to, statements related to the potential of Gritstone's therapeutic programs; the advancements in the company's ongoing clinical trials; the timing of data announcements related to ongoing clinical trials and the initiation of future clinical trials. 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 Quarterly Report on Form 10-Q filed on August 4, 2022 and any current and periodic reports filed with the Securities and Exchange Commission.

## **Gritstone Contacts**

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**Gritstone bio, Inc.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**  
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Revenues:</b>				
Collaboration and license revenues	\$ 2,761	\$ 2,843	\$ 7,506	\$ 42,536
Grant revenues	2,710	—	5,156	—
Total revenue	<u>5,471</u>	<u>2,843</u>	<u>12,662</u>	<u>42,536</u>
<b>Operating expenses:</b>				
Research and development	27,347	22,072	55,546	46,928
General and administrative	7,792	5,937	15,747	12,878
Total operating expenses	<u>35,139</u>	<u>28,009</u>	<u>71,293</u>	<u>59,806</u>
Loss from operations	(29,668)	(25,166)	(58,631)	(17,270)
Interest income, net	153	48	200	75
Net loss	<u>(29,515)</u>	<u>(25,118)</u>	<u>(58,431)</u>	<u>(17,195)</u>
Net loss per share, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.33)</u>	<u>\$ (0.68)</u>	<u>\$ (0.23)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>86,448,632</u>	<u>76,749,641</u>	<u>86,363,116</u>	<u>76,368,506</u>

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

	June 30, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 65,694	\$ 93,287
Marketable securities	78,939	108,346
Restricted cash	9,311	11,285
Prepaid expenses and other current assets	7,791	7,672
Total current assets	161,735	220,590
Restricted cash	5,290	6,005
Property and equipment, net	22,712	21,622
Lease right-of-use assets	21,126	22,920
Deposits and other long-term assets	3,090	2,352
Long-term marketable securities	—	4,617
Total assets	<u>\$ 213,953</u>	<u>\$ 278,106</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,381	\$ 4,230
Accrued compensation	5,331	6,925
Accrued liabilities	2,035	411
Accrued research and development expenses	4,386	3,706
Lease liabilities, current portion	7,174	7,483
Deferred revenue, current portion	11,079	17,201
Total current liabilities	32,386	39,956
Lease liabilities, net of current portion	17,800	18,936
Deferred revenue, net of current portion	389	3,128
Total liabilities	50,575	62,020
Commitments and contingencies		
Stockholders' equity:		
Common stock	20	20
Additional paid-in capital	623,583	617,523
Accumulated other comprehensive loss	(410)	(73)
Accumulated deficit	(459,815)	(401,384)
Total stockholders' equity	163,378	216,086
Total liabilities and stockholders' equity	<u>\$ 213,953</u>	<u>\$ 278,106</u>

