

**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 17, 2021

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 Number)

**5959 Horton Street, Suite 300
Emeryville, California 94608**
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (510) 871-6100

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, par value \$0.0001	GRTS	The 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 8.01 Other Events.

On August 17, 2021, Gritstone bio, Inc. (the “Company” or “Gritstone”) announced that it entered into a funding agreement with the Coalition for Epidemic Preparedness Innovations (CEPI) for up to \$20.6 million to advance the development of Gritstone’s CORAL COVID-19 vaccine program with an initial focus in South Africa. Under the terms of the agreement, CEPI will fund a multi-arm Phase I study evaluating the CORAL program’s SAM vaccine in naïve, convalescent, and HIV positive patients. The funding will also support pre-clinical studies, scale-up and formulation development to enable more stable drug product.

A copy of the press release with the foregoing announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 17, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GRITSTONE BIO, INC.

Date: August 17, 2021

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



Gritstone and CEPI Announce Agreement to Advance Second-Generation COVID-19 Vaccine Program (CORAL) Against SARS-CoV-2 Variants of Concern

- *CEPI to fund Gritstone’s work on second-generation vaccines against SARS-CoV-2, the virus causing COVID-19, including a clinical trial in South Africa and manufacturing optimization*
- *Gritstone’s second-generation vaccines include self-amplifying mRNA (SAM) to deliver multiple antigens (spike protein plus additional sequence from non-spike genes) providing the potential for deep, broad, and durable immunity against SARS-CoV-2 variants*
- *Gritstone’s CORAL Phase 1 program – which includes the CEPI-funded trial—is establishing optimal dosing and antigenic content in young individuals, the elderly, the previously vaccinated, and the immunocompromised, including people living with HIV*

EMERYVILLE, CALIF. – August 17, 2021 (GLOBE NEWSWIRE) – Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, today announced that the company entered into a funding agreement of up to \$20.6 million with the Coalition for Epidemic Preparedness Innovations (CEPI) to advance the development of Gritstone’s CORAL COVID-19 vaccine program with an initial focus in South Africa.

“COVID-19 variants are already rendering some of our vaccines less effective, so it is critical that we don’t let our guard down: we must continue to invest in critical vaccine R&D if we are to stay one step ahead of this deadly virus,” said Richard Hatchett, M.D., CEO of CEPI. “CEPI is planning for the longer-term management of COVID-19 by investing in vaccines to address the threat of variants, and I’m pleased to work with Gritstone to advance the development of this innovative vaccine candidate which can be made globally accessible through COVAX if it is proven to be safe and effective.”

“Our unique approach combines our self-amplifying mRNA platform with a broad set of viral antigens beyond spike intended to drive robust and durable immune responses comprising both neutralizing antibodies and CD8+ T cells. With this unique antigenic breadth, our CORAL vaccine may offer protection against emerging spike variants of SARS-CoV-2 that appear challenging for first generation vaccines,” said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. “We are honored to be supporting CEPI in their mission to help find new vaccine solutions to battle this deadly virus on a global scale and help prevent current and perhaps future COVID outbreaks.”

Professor Shabir Madhi, dean of the Faculty of Health Sciences and professor of vaccinology at the University of the Witwatersrand, Johannesburg, South Africa and a member of the WHO Strategic Advisory Group of Experts on Immunization (SAGE) commented, “The ongoing mutations in SARS-CoV-2 leading to increased transmissibility and relative immune evasion from most first generation COVID-19 vaccines that primarily target the spike protein, call for alternate approaches aimed at driving CD8+ immunity against spike and more conserved epitopes. This could assist in reducing both infectiousness of breakthrough cases and overall virus transmission.” Professor Mahdi will lead the Gritstone clinical trial in South Africa.

Under the terms of the agreement, CEPI will fund a multi-arm Phase 1 study evaluating the CORAL program's SAM vaccine in naïve, convalescent, and HIV+ patients. The funding will also support pre-clinical studies, scale-up and formulation development to enable more stable drug product. The study will evaluate two different SAM vaccine constructs that each target both the spike protein and other SARS-CoV-2 targets and are designed to drive both robust B and T cell immune responses. The trial is expected to initiate before the end of 2021.

CEPI is committed to global equitable access to COVID-19 vaccines so, through this agreement, CEPI and Gritstone bio have agreed that this vaccine candidate will be made available to the COVAX Facility for procurement and allocation, if proven to be safe and effective. The COVAX Facility aims to deliver equitable access to COVID-19 vaccines for all countries, at all levels of development, that wish to participate.

About the CORAL Program

Gritstone's CORAL program is a second-generation SARS-CoV-2 vaccine platform delivering spike and additional SARS-CoV-2 T cell epitopes, offering the potential for deep, broad, and durable protection against SARS-CoV-2 variants. Delivery vectors can comprise a chimpanzee adenovirus, self-amplifying mRNA or both. The program is supported by several key relationships: La Jolla Institute for Immunology, Bill & Melinda Gates Foundation, National Institute of Allergy and Infectious Disease (NIAID), and the Coalition for Epidemic Preparedness Innovations (CEPI). A Phase 1 clinical trial is currently being sponsored by NIAID examining the reactogenicity and immunogenicity of CORAL in healthy volunteers and as a booster for previously vaccinated volunteers. Gritstone is sponsoring and conducting its own Phase 1 studies in select populations, which are anticipated to begin before the end of 2021. Together with the CEPI supported study, this set of clinical trials will test four different vaccine candidates and establish optimal dosing and antigenic content for the CORAL program in young individuals, the elderly, the previously vaccinated, and the immunocompromised.

About Gritstone

Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company, is developing the next generation of immunotherapies against multiple cancer types and infectious diseases. Gritstone develops its products by leveraging two key pillars—first, a proprietary AI -based platform, Gritstone EDGETM, which is designed to predict antigens that are presented on the surface of cells, such as tumor or virally-infected cells, that can be seen by the immune system; and, second, the ability to develop, manufacture, and deliver selected antigens to the patient's immune system to drive the destruction of tumors or virally-infected cells. . The company's lead oncology programs include an individualized neoantigen-based immunotherapy, GRANITE, and an "off-the-shelf" shared neoantigen-based immunotherapy, SLATE, which are being evaluated in clinical studies. Within its infectious disease pipeline, Gritstone is advancing CORAL, a COVID-19 program to develop a second-generation vaccine, with support from departments within the National Institutes of Health (NIH), the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI) and through a license agreement with La Jolla Institute for Immunology. Additionally, the company has a global collaboration for the development of a therapeutic HIV vaccine with Gilead Sciences. For more information, please visit gritstone.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' early 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 5, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.