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): September 27, 2023

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 1.01 Entry into a Material Definitive Agreement.

On September 27, 2023, Gritstone bio, Inc. (the "Company") entered into a contract (the "BARDA 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. Under the BARDA Contract, the Company will receive funding of up to an estimated $433 million to conduct a 10,000 participant randomized Phase 2b comparative study evaluating the Company's next-generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19.

The BARDA Contract could result in payments to the Company of up to approximately $433 million. The BARDA Contract consists of a base period (ending on or before the first quarter of 2024) and a total contract period-of-performance (base period plus two stages gated at BARDA's discretion) of up to approximately four years. The base period for the BARDA Contract includes government funding of up to approximately $10 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. Following successful completion of the base period, the BARDA Contract provides for approximately $423 million of additional BARDA funding for two stages gated at BARDA's discretion in support of the clinical trial execution and additional analyses for the clinical trial.

The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

The Company estimates that, based on the fees payable and anticipated reimbursement of certain expenses to the Company under the BARDA Contract, the Company's cash runway will be extended into the fourth quarter of 2024.

The foregoing description of the BARDA Contract does not purport to be complete and is qualified in its entirety by reference to the full text of the BARDA Contract, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2023.

Item 7.01. Regulation FD Disclosure.

On September 27, 2023, the Company issued a press release announcing its entry into the BARDA Contract, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information in this Item 7.01 to this Current Report on Form 8-K, and in Exhibit 99.1 furnished herewith, shall not be deemed to be "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 such information 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 a filing.

Forward-Looking Statements

This report contains forward-looking statements, including, but not limited to, statements related to the Company's clinical and regulatory development plans for its product candidates; expectations regarding the data to be derived in the Company's ongoing and planned clinical trials; the timing of funds pursuant to the BARDA Contract and expectations regarding the Company's cash runway. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated September 27, 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: September 27, 2023

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

Exhibit 99.1

Gritstone bio Awarded BARDA Contract to Conduct Comparative Phase 2b Study Evaluating Next-Generation Vaccine Candidate for COVID-19 Valued at up to $433 Million

— 10,000 participant randomized Phase 2b study will evaluate Gritstone's self-amplifying mRNA (samRNA) vaccine candidate containing Spike plus other viral targets with an approved vaccine against COVID-19 —

— Contract is part of 'Project NextGen,' an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19 —

EMERYVILLE, CALIF. – September 27, 2023 (GLOBE NEWSWIRE) – Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, announced today that it was awarded a contract by the Biomedical Advanced Research and Development Authority (BARDA) to conduct a Phase 2b comparative study evaluating Gritstone's self-amplifying mRNA (samRNA) vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The agreement, which is valued at up to $433 million, was awarded as part of 'Project NextGen,' an initiative by the U.S. Department of Health and Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19.

Under the contract, Gritstone bio will conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of the Gritstone next-generation COVID-19 vaccine candidate with an approved COVID-19 vaccine. Preparations for the study are underway, and execution of the study will be fully funded by BARDA. Gritstone will run the study in the United States in collaboration with the COVID-19 Prevention Network (CoVPN), a NIAID-supported network of clinical trial sites based at Fred Hutchinson Cancer Center with experience conducting large COVID-19 vaccine trials.

"We are honored to receive this award from BARDA to advance our next-generation samRNA vaccine against COVID-19 (the CORAL program), which provides strong validation of our innovative vaccine platform in infectious diseases. Not only does this contract supply the necessary resources to advance the development of CORAL, but it also signifies the trust and confidence the U.S. government has placed in our novel vaccine approach," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "First-generation COVID-19 vaccines provided great utility during the height of the pandemic but are limited in breadth and durability of clinical protection. CORAL was designed to address these limitations by inducing durable neutralizing antibody and T cell-based immunity against current and future SARS-CoV-2 variants. Across multiple Phase 1 studies, our samRNA vaccine, which incorporates both Spike and other viral targets (Spike plus), has demonstrated induction of potent immune responses with potential to drive broad and durable clinical protection – this potential will now be tested in a randomized setting. We are excited about this opportunity to work alongside BARDA and look forward to initiating the Phase 2b study (CORAL-BARDA) in the first quarter of 2024. With CORAL moving into a randomized Phase 2 study alongside our personalized cancer vaccine program (GRANITE), Gritstone now sits at the precipice of unlocking the full potential of our novel vaccine platforms in both oncology and infectious diseases."

This project has been funded with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50123C00062.

About the CORAL Program

Gritstone's CORAL program is applying Gritstone's infectious disease approach for the prevention of COVID-19. The program aims to drive both B cell and T cell immunity using self-amplifying mRNA (samRNA) and novel immunogens containing Spike plus additional viral targets. To date, the CORAL program has comprised three Phase 1 trials evaluating multiple samRNA vaccine candidates across various patient populations and settings: CORAL-BOOST (healthy volunteers following primary series of currently approved COVID-19 vaccines); CORAL-CEPI (vaccine-naïve healthy and HIV+ subjects in South Africa); and CORAL-NIH (run by the National Institute of Allergy and Infectious Disease [NIAID] in previously vaccinated healthy volunteers). Results to date have demonstrated induction and persistence of high neutralizing antibody levels through at least 6 months as well as broad T cell responses. The CORAL program is supported by Biomedical Advanced Research and Development Authority (BARDA), NIAID, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill & Melinda Gates Foundation.

About Self-amplifying mRNA (samRNA)

Self-amplifying mRNA (samRNA) is rapidly emerging as a well-tolerated, scalable and widely-applicable platform technology which can be used to develop multiple vaccines simply by changing the sequence of the antigen (the target of the immune system) that is encoded in the vector RNA and delivered in a lipid nanoparticle. Like traditional mRNA vaccines, samRNA vaccines use the host cell's translation system to convert mRNA to protein target antigens in order to stimulate immunity. Unlike traditional mRNA, samRNA creates multiple copies of the antigen RNA once in the cell, potentially leading to extended duration and magnitude of antigen expression. Gritstone designs novel immunogens, the vaccine regions encoding virus antigens, and includes both Spike antigen (similar to first-generation COVID-19 vaccines) and evolutionarily conserved, non-Spike antigens likely to drive T cell responses in its next-generation COVID-19 vaccines. Potential benefits of this samRNA "Spike plus" approach include (1) strong and durable induction of neutralizing antibodies to Spike, (2) broad and durable T cell immunity (CD4+ and CD8+) to multiple viral proteins, (3) potency at lower doses (dose sparing), and (4) refrigerator stability.

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 9, 2023 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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