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): December 12, 2019

Gritstone Oncology, 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 Number)

5858 Horton Street, Suite 210
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 December 12, 2019, Gritstone Oncology, Inc. (the "Company") presented preliminary immunogenicity data from the Phase 1 GO-004 clinical study of GRANITE, the Company's personalized immunotherapy product candidate, at the European Society for Medical Oncology's Immuno-Oncology Congress.

A copy of the press release discussing the preliminary immunogenicity data 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.

Exhibit No.	Description
99.1	Press Release, dated December 12, 2019

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 ONCOLOGY, INC.

Date: December 13, 2019

By: /s/ Jean-Marc Bellemin
Jean-Marc Bellemin
Executive Vice President, Chief Financial Officer

Exhibit 99.1

Gritstone Oncology Reports Promising Early Immunogenicity Activity and Safety Data from its Phase 1 Studies Evaluating its Neoantigen-based Immunotherapies, GRANITE and SLATE

-- Preliminary results demonstrate unprecedented levels of primed CD8+ neoantigen-specific cytotoxic T cells and expansion of pre-existing T cells even in low-dose cohorts –

— Investor conference call and webcast at 8:00 am ET today —

EMERYVILLE, CALIF. – December 12, 2019 (GLOBE NEWSWIRE) – Gritstone Oncology, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing the next generation of cancer immunotherapies to fight multiple cancer types, today announced that the company has presented preliminary Phase 1 GRANITE immunogenicity data demonstrating the rapid, robust and consistent induction of large numbers of $CD8^+$ T cells against multiple neoantigens in four solid tumor patients with available IFN-g ELISpot data (up to 3,000 IFN-g spot forming units per 10^6 PBMCs were generated, as measured by overnight ELISpot) within the first two dosing cohorts. Importantly, these T cells were also able to produce IL-2 and Granzyme B, demonstrating that they have cytotoxic potential. In addition to priming naive $CD8^+$ T cells against encoded neoantigens, the data demonstrate that GRANITE can also stimulate the expansion of pre-existing T-cell populations. Safety data from five patients receiving GRANITE and three patients receiving SLATE across the first two dose levels indicate that the immunotherapies were well-tolerated with no dose-limiting toxicities observed. Dose escalation continues. These results were presented today in an oral session at the European Society for Medical Oncology (ESMO) Immuno-Oncology Congress in Geneva, Switzerland.

“We are thrilled to observe very robust, polyfunctional $CD8^+$ T cells against predicted neoantigens even at the first dose level of our phase 1 study,” said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. “We view these preliminary results as important de-risking data, demonstrating the unprecedented immunogenicity of our heterologous prime/boost vaccine platform at its lowest dose, in combination with nivolumab. Pre-clinical data have shown a clear dose response where higher doses of the self-amplifying RNA boost vaccination, as well as the addition of anti-CTLA-4, further increase the number and function of $CD8^+$ T cells. Notably, the starting dose of self-amplifying RNA was conservative since this is the first in-human study with this therapeutic approach. Therefore, we look forward to presenting mature data at higher doses with additional patients receiving the full immunotherapy regimen in several months.”

In the GRANITE Phase 1 GO-004 study, the first dosing cohort consisted of three advanced cancer patients, including two gastroesophageal adenocarcinoma patients and one non-small cell lung cancer patient who had previously progressed on prior anti-PD-L1 therapy. From the second GRANITE dosing cohort, early ELISpot data was available from one microsatellite-stable

colorectal cancer patient. Most common adverse events in the GO-004 study were grade 1/2 fever and skin rash, consistent with an inflammatory immune reaction. In the SLATE Phase 1 GO-005 study, patients are still early in their course of treatment, and treatment-related adverse events have been limited to one injection site reaction and one case of grade 1/2 pruritus.

About GRANITE and SLATE Ongoing Phase 1/2 Clinical Studies

Gritstone's GRANITE personalized immunotherapy delivers a cassette of 20 TSNA identified by the company using its proprietary Gritstone EDGE™ artificial intelligence platform and tumor HLA peptide sequencing, representing tumor-specific neoantigens that are derived from the patient's own tumor. GRANITE is being evaluated in combination with immune checkpoint blockade in a Phase 1/2 clinical study, referred to as GO-004, for the treatment of patients with advanced solid tumors, including microsatellite-stable colorectal cancer (MSS CRC), gastroesophageal cancer, metastatic non-small cell lung cancer, and bladder cancer. In the Phase 1 study, all patients receive a fixed dose of intramuscular adenovirus-based prime with three escalating doses (30, 100 and 300 µg) of intramuscular RNA-based boost vaccinations in combination with intravenous anti-PD-1 therapy. Following dose escalation of the RNA-based boost vaccine to 100 µg, subcutaneous anti-CTLA-4 is added to the treatment regimen in the third dosing cohort. GRANITE was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of MSS CRC.

Gritstone's SLATE "off-the-shelf" immunotherapy delivers a cassette of 20 TSNA identified by the company using its proprietary EDGE artificial intelligence platform and tumor HLA peptide sequencing, representing mutated gene sequences that are shared across patients (such as K-RAS mutations). SLATE is being evaluated in combination with immune checkpoint blockade in a Phase 1/2 clinical study called GO-005 for the treatment of patients with advanced solid tumors, including metastatic non-small cell lung cancer, pancreatic ductal adenocarcinoma and microsatellite-stable colorectal cancer, as well as in patients with other solid tumor types who have relevant mutation/HLA (human leukocyte antigen) combinations. In the Phase 1 study, all patients receive a fixed dose of intramuscular adenovirus-based prime with three escalating doses (30, 100 and 300 µg) of intramuscular RNA-based boost vaccinations in combination with intravenous anti-PD-1 therapy. Following dose escalation of the RNA-based boost vaccine to 30 µg, subcutaneous anti-CTLA-4 is added to the treatment regimen in the second dosing cohort.

Investor Teleconference and Webcast

The company will host a conference call today, December 12, 2019 at 8:00 am ET to review its clinical programs, including the clinical data presented at ESMO-IO. The conference call can be accessed by dialing (866) 866-1333 or (404) 260-1421 and referencing conference ID number 49260042. A webcast of the call and accompanying slides will be available within the Investors & Media section of the Gritstone Oncology website at https://ir.gritstoneoncology.com/investors/events. An archived replay will be accessible for 30 days following the event.

About Gritstone Oncology

Gritstone Oncology (Nasdaq: GRTS), a clinical-stage biotechnology company, is developing the next generation of cancer immunotherapies to fight multiple cancer types. Gritstone develops its products by leveraging two key pillars—first, a proprietary machine learning-based platform, Gritstone EDGE™, which is designed to predict, from a routine tumor biopsy, the tumor-specific neoantigens (TSNA) that are presented on a patient's tumor cells; and second, the ability to develop and manufacture potent immunotherapies utilizing patients' TSNA to potentially drive the patient's immune system to specifically attack and destroy tumors. The company's lead product candidate, GRANITE, is a personalized neoantigen-based immunotherapy in Phase 1 clinical testing. Gritstone's second product candidate, SLATE, is a shared neoantigen, "off-the-shelf" immunotherapy which is also being evaluated in a Phase 1 clinical study. Novel tumor-specific antigens can also provide targets for bispecific antibody (BiSAb) therapeutics for solid tumors, and Gritstone's BiSAb program is currently in lead optimization. For more information, please visit gritstoneoncology.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. 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 November 12, 2019 and any current and periodic reports filed with the Securities and Exchange Commission.

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