



Gritstone Reports First Quarter 2021 Financial Results and Business Highlights

May 6, 2021

EMERYVILLE, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, today reported financial results for the first quarter ended March 31, 2021 and reviewed business highlights.

"The momentum we generated in the first quarter -- with the launch of two novel programs in a new therapeutic category of infectious disease, the execution of multiple collaborations with notable government, private and nonprofit institutions, and the continued advancement of our oncology clinical programs -- reflects the significant interest in our innovative, antigen-directed clinical-stage immunotherapies," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. "We expect this activity level to extend into the rest of the year. We are continuing patient dosing and follow-up in our GRANITE program and will be submitting these data for presentation at ESMO. Additionally, we expect to have data from our CORAL COVID-19 program available later this year. Finally, we will be initiating multiple clinical studies in oncology and infectious disease in 2021."

Key Accomplishments

Neoantigen Oncology Programs

- Continued enrolling and treating patients with advanced cancer in single-arm Phase 2 expansion cohorts with GRANITE, an individualized neoantigen immunotherapy, as a late-line therapy for metastatic microsatellite stable colorectal cancer (MSS-CRC), gastroesophageal (GEA) cancer and non-small cell lung cancer (NSCLC)
- Continued enrolling and treating patients in single-arm Phase 2 expansion cohorts with version 1 (v1) of SLATE, a shared neoantigen immunotherapy

Infectious Disease Programs

- Announced the launch of our CORAL COVID-19 program to develop a second-generation vaccine against SARS-CoV-2, the virus that causes COVID-19, with potential for both more durable protection and broader immunity against Spike and additional non-Spike antigens, compared with first-generation "Spike-only" vaccines which can be impacted by emerging variants of concern in Spike sequence
- Began dosing volunteers in a Phase 1 CORAL clinical trial, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) and conducted through the Infectious Diseases Clinical Research Consortium (IDCRC)
- Established a collaboration with Gilead Sciences (Gilead) to develop a vaccine-based immunotherapy as part of Gilead's efforts to find a curative treatment for human immunodeficiency virus (HIV) infection, and received \$60 million in proceeds as a part of the collaboration

Anticipated Remaining 2021 Milestones

- Submit an abstract to the European Society for Medical Oncology (ESMO) conference in September 2021 to present GRANITE data, including longer-term follow-up of late-stage, advanced disease patients who remain in the Phase 1 study, in addition to preliminary data from the Phase 2 cohorts in the same disease context
- Advance the SLATE program by initiating a study with the version two (v2) cassette optimized for KRAS neoantigens for patients with NSCLC, and sharing data from SLATE v1 cohorts in the third quarter of 2021
- Initiate a company-sponsored COVID-19 clinical study in the third quarter of 2021, evaluating a novel vaccine containing Spike and other SARS-CoV-2 epitopes as a boost after first generation vaccination
- Share NIAID-IDCRC Phase 1 COVID-19 vaccine data in the third quarter of 2021
- Share initial COVID-19 vaccine boost data in the fourth quarter of 2021
- Initiate two randomized Phase 2 trials of GRANITE in earlier-stage cancer patients in the second half of 2021
- Launch a new SLATE program, centered on an undisclosed shared neoantigen, at the end of 2021

First Quarter 2021 Financial Results

For the three months ended March 31, 2021, Gritstone reported net income of \$7.9 million, compared to a net loss of \$26.2 million for the three months ended March 31, 2020. The increase in net income was due to an increase in license fee revenue.

Collaboration and license revenue was \$39.7 million for the three months ended March 31, 2021, compared to \$1.3 million for the three months ended March 31, 2020. The increase was due to the license revenue associated with the Gilead Collaboration Agreement entered into in January 2021.

Total research and development expenses were \$24.9 million for the three months ended March 31, 2021, compared to \$22.5 million for the three months ended March 31, 2020. The increase was primarily attributable to an increase in milestone and license payments, as well as personnel-related expenses.

General and administrative expenses were \$6.9 million for the three months ended March 31, 2021, compared to \$5.5 million for the three months ended March 31, 2020. The increase was primarily attributable to an increase in outside professional services.

Cash, cash equivalents, marketable securities and restricted cash were \$199.0 million as of March 31, 2021 compared to \$172.1 million as of December 31, 2020.

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 machine learning-based platform, Gritstone EDGE™, 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 and manufacture potent immunotherapies utilizing these antigens to potentially drive the patient's immune system to specifically attack and destroy disease-causing 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, as well as 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 May 6, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.

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Gritstone bio, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2021	2020
Revenue:		
Collaboration and license revenues	\$ 39,693	\$ 1,262
Total revenue	39,693	1,262
Operating expenses:		
Research and development	24,856	22,468
General and administrative	6,941	5,465
Total operating expenses	31,797	27,933
Income (loss) from operations	7,896	(26,671)
Interest and other income, net	\$ 27	\$ 465
Net income (loss)	\$ 7,923	\$ (26,206)
Net income (loss) per common share, basic	\$ 0.10	\$ (0.71)
Shares used to compute for net income (loss) per common share, basic and diluted	75,987,372	36,798,562
Net income (loss) per common share, diluted	\$ 0.10	\$ (0.71)

Shares used to compute for net income (loss) per common share, basic and diluted

77,464,356 36,798,562

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 108,505	\$ 170,056
Marketable securities	89,501	1,002
Prepaid expenses and other current assets	4,507	4,332
Total current assets	202,513	175,390
Property and equipment, net	21,693	22,105
Operating lease right-of-use assets	19,997	21,344
Deposits and other long-term assets	2,736	2,728
Total assets	\$ 246,939	\$ 221,567
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,368	\$ 9,578
Accrued compensation	3,821	6,331
Accrued liabilities	571	677
Accrued research and development	1,558	1,053
Lease liabilities, current portion	6,075	5,874
Deferred revenue, current portion	3,386	3,475
Total current liabilities	21,779	26,988
Other non-current liabilities	395	395
Lease liabilities, net of current portion	17,619	19,225
Deferred revenue, net of current portion	7,795	8,220
Total liabilities	47,588	54,828
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	18	18
Additional paid-in capital	517,715	493,023
Accumulated other comprehensive loss	(3)	-
Accumulated deficit	(318,379)	(326,302)
Total stockholders' equity	199,351	166,739
Total liabilities and stockholders' equity	\$ 246,939	\$ 221,567

