



Gritstone Reports First Quarter 2022 Financial Results and Provides Business Update

May 6, 2022

-- Clinical programs continue progressing, with multiple Phase 2 data catalysts from neoantigen oncology vaccine programs and additional human data evaluating self-amplifying mRNA (samRNA) vaccines against viruses expected over the next 18 months --

-- Recent presentations reinforce expertise in vaccine design and delivery and potential of Gritstone's platform technologies in oncology and infectious diseases --

-- Cash, cash equivalents, marketable securities and restricted cash of \$186.8 million as of March 31, 2022 --

EMERYVILLE, Calif., May 06, 2022 (GLOBE NEWSWIRE) -- In a release issued under the same headline on May 5, 2022 by Gritstone bio, Inc. (Nasdaq: GRTS), please note that two values in the Condensed Consolidated Statements of Operations table and one value in the Condensed Consolidated Balance Sheets table were erroneously reported. The corrected release follows:

Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company that aims to develop the world's most potent vaccines, today reported financial results for the first quarter ended March 31, 2022 and reviewed business highlights.

"Clinical data out of our cancer and viral disease vaccine programs are expected to be flowing steadily through year-end and over the next 18 months," said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. "Our individualized neoantigen vaccine candidate for solid tumors, GRANITE, is now in a randomized Phase 2/3 trial in newly diagnosed metastatic colorectal cancer, building on the exciting molecular response/survival data shown at ESMO 2021 in end-stage colorectal cancer patients. Multiple Phase 1 trials are ongoing in CORAL (2nd generation COVID-19 vaccine program) with data from all studies expected throughout 2H2022, and initial data from the Phase 2 study of SLATE-KRAS (KRAS-specific 'off-the-shelf' vaccine candidate) is also expected in 2H2022. Our recent presentations at AACR underscore the unique capabilities of our novel self-amplifying mRNA (samRNA) vector, which has demonstrated potency and dose sparing potential along with a favorable safety and tolerability profile in the clinic. The data we are generating with SARS-CoV-2 as the target are providing validation for the entire samRNA platform and provide clear rationale to pursue additional viral pathogens. We look forward to sharing more data and continuing to demonstrate the value we are bringing to patients and all stakeholders as the year progresses."

Clinical Program Updates

Tumor-Specific Neoantigen (TSNA) Oncology Programs

GRANITE – Individualized, TSNA-directed vaccine-based immunotherapy using an adenoviral priming vector and samRNA boost vector to deliver relevant neoantigens. Following success in late-line studies, Gritstone intends to continue advancing GRANITE through randomized, controlled trials and evaluate these candidates in earlier lines of treatment, where immune responses may be stronger and the potential benefits could be further accentuated.

- In January, Gritstone announced the first patient was enrolled for inclusion in 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). Preliminary data (molecular response and progression-free survival) from the Phase 2 portion of the trial are expected in 2H2023.
- In March, Gritstone announced the first patient was enrolled for inclusion in GRANITE-CRC-ADJUVANT, a randomized, controlled Phase 2 trial in patients with high risk MSS-CRC and stage II/III disease who are circulating tumor DNA (ctDNA)+ after definitive surgery.
- In April, Gritstone shared two poster presentations at the American Association for Cancer Research (AACR) Annual Meeting:
 - [Poster 1238](#) further demonstrated the correlation between patient survival and ctDNA in metastatic CRC.
 - [Poster 4149](#) demonstrated lower doses of samRNA drive superior neoantigen-specific CD8+ T cell responses in cancer patients versus high doses in Phase 1/2 trials for GRANITE and SLATE in patients with advanced solid tumors.

SLATE – "Off-the-shelf" shared neoantigen-directed vaccine-based immunotherapy using an adenoviral priming vector and samRNA boost vector to deliver a cassette of shared TSNA. 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 tumor-specific targets across a number of patient populations and cancer types.

- In April, Gritstone presented an [oral presentation](#) at AACR detailing how translational immunology data and the company's cassette design capabilities enabled development of SLATE-KRAS, an optimized, KRAS-specific version of SLATE that is now in Phase 2 study 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 our original candidate, SLATE v1.
- o Initial data from the ongoing Phase 2 study of SLATE-KRAS trial are expected in 2H2022.

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. This approach has demonstrated the ability to generate robust CD8+ T cells and neutralizing antibodies against SARS-CoV-2 in multiple preclinical and clinical studies and is being evaluated against multiple other pathogens in Gritstone-owned and partnered studies.

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 products by inducing potent CD8+ T cells in addition to neutralizing antibody responses.

- Gritstone is currently evaluating five distinct SARS-CoV-2 product candidates across four different clinical trials containing Spike plus additional non-Spike TCE sequences (and also full-length nucleocapsid). These studies include homologous and heterologous prime-boost regimens. All four of these studies are ongoing, and initial data from all are expected during the second half of 2022.
 - o The CORAL-BOOST study, a Phase 1 study evaluating a T cell enhanced samRNA vaccine as a booster against SARS-CoV-2, is ongoing in the United Kingdom. In January, Gritstone announced positive clinical data from the first cohort and subsequently expanded the study. The data, which demonstrated both strong neutralizing antibody responses to Spike and robust CD8+ T cell responses, provided human proof of concept of the samRNA vector in viral diseases and the company's approach to infectious disease.
 - 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 constructs in virus-naïve, convalescent, and HIV+ patients.
 - o The CORAL-IMMUNOCOMPROMISED trial is ongoing in the United Kingdom evaluating T cell enhanced samRNA and chimpanzee adenovirus (ChAd) vaccines in B cell deficient subjects.
 - 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 ChAd 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.

First Quarter 2022 Financial Results

Cash, cash equivalents, marketable securities and restricted cash were \$186.8 million as of March 31, 2022, compared to \$223.5 million as of December 31, 2021.

Research and development expenses were \$28.2 million for the three months ended March 31, 2022, compared to \$24.9 million for the three months ended March 31, 2021. The increase of \$3.3 million for the three months ended March 31, 2022 compared to the three months ended March 31, 2021 was primarily due to increases in personnel-related expenses, outside services, and facilities related costs, offset by decreases in laboratory supplies and milestone and license payments.

General and administrative expenses were \$8.0 million for the three months ended March 31, 2022, compared to \$6.9 million for the three months ended March 31, 2021. The increase of \$1.1 million was primarily attributable to increases in personnel-related expenses and in facilities-related costs, offset by a decrease in outside services.

Collaboration and license revenue was \$4.7 million for the three months ended March 31, 2022, compared to \$39.7 million for the three months ended March 31, 2021. During the three months ended March 31, 2022, we recognized \$4.0 million in collaboration revenue related to the 2seventy Agreement, \$0.7 million in collaboration revenue related to the Gilead Collaboration Agreement, \$2.2 million in grant revenue from the CEPI Funding Agreement, and \$0.2 million in grant revenue from the Gates Foundation. During the three months ended March 31, 2021, we recorded \$38.6 million in license revenue and \$0.3 million in collaboration revenue related to the Gilead Collaboration Agreement and \$0.7 million in collaboration revenue related to the 2seventy Agreement.

About Gritstone

Gritstone bio, Inc. (Nasdaq: GRTS) is a clinical-stage biotechnology company that aims to create the world's most potent vaccines. Experts in vaccine design and development, 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 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 5, 2022 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 amounts)

	Three Months Ended March 31,	
	2022	2021
Collaboration and license revenues	\$ 4,745	\$ 39,693
Grant revenues	2,446	-
Total revenues	7,191	39,693
Operating expenses:		
Research and development	28,199	24,856
General and administrative	7,955	6,941
Total operating expenses	36,154	31,797
Income (loss) from operations	\$ (28,963)	\$ 7,896
Interest income, net	\$ 47	\$ 27
Net income (loss)	\$ (28,916)	\$ 7,923
Net income (loss) per common share, basic	\$ (0.34)	\$ 0.10
Weighted-average number of shares used in computing net income (loss) per share, basic	86,277,599	75,987,372
Net income (loss) per share, diluted	\$ (0.34)	\$ 0.10
Weighted-average number of shares used in computing net income (loss) per share, diluted	86,277,599	77,464,356

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 69,158	\$ 93,287

Marketable securities	103,004	108,346
Restricted cash	9,395	11,285
Prepaid expenses and other current assets	10,946	7,672
Total current assets	192,503	220,590
Restricted cash	5,290	6,005
Property and equipment, net	22,283	21,622
Lease right-of-use assets	21,832	22,920
Deposits and other long-term assets	1,564	2,352
Long-term marketable securities	-	4,617
Total assets	<u>\$ 243,472</u>	<u>\$ 278,106</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,641	\$ 4,230
Accrued compensation	4,285	6,925
Accrued liabilities	1,350	411
Accrued research and development	3,601	3,706
Lease liabilities, current portion	6,886	7,483
Deferred revenue, current portion	12,324	17,201
Total current liabilities	34,087	39,956
Other non-current liabilities		
Lease liabilities, net of current portion	18,989	18,936
Deferred revenue, net of current portion	1,505	3,128
Total liabilities	54,281	62,020
Commitments and contingencies		
Convertible preferred stock	-	-
Common stock	20	20
Additional paid-in capital	619,862	617,523
Accumulated other comprehensive loss	(391)	(73)
Accumulated deficit	(430,300)	(401,384)
Total stockholders' equity	189,191	216,086
Total liabilities and stockholders' equity	<u>\$ 243,472</u>	<u>\$ 278,106</u>

