Gritstone bio Reports Third Quarter 2023 Financial Results and Provides Corporate Updates

November 8, 2023

-- BARDA contract and IDWeek presentations position Gritstone's self-amplifying mRNA (samRNA) as a leading next-generation approach to COVID-19 prevention; preparations underway for Phase 2b head-to-head study evaluating samRNA candidate versus an approved COVID-19 vaccine --

-- Preliminary data from Phase 2 portion of Phase 2/3 study evaluating Gritstone's personalized cancer vaccine (PCV), GRANITE, in first-line metastatic, microsatellite stable colorectal cancer (MSS-CRC) remain expected in 1Q 2024 --

-- Investigational new drug application (IND) cleared for National Cancer Institute (NCI)-run Phase 1 study evaluating an autologous T cell therapy in combination with Gritstone's "off-the-shelf" cancer vaccine, SLATE-KRAS --

-- Cash, cash equivalents, marketable securities and restricted cash of $90.5 million as of September 30, 2023 --

EMERYVILLE, Calif., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today reported financial results for the third quarter ended September 30, 2023 and provided recent corporate and clinical updates.

"As cancer and infectious diseases continue to challenge human health across the globe, we at Gritstone continue advancing our vision to deliver more potent and durable vaccines," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "The ongoing advancement of our CORAL program positions our infectious disease approach, which combines self-amplifying mRNA (samRNA) with novel B and T cell targets, as a leading potential next-generation vaccine platform for COVID-19 and beyond. We believe the data recently shared at IDWeek underscore the promise of this novel approach to drive broad and long-lasting clinical protection against COVID-19 with vaccine-elicited neutralizing antibodies against the virus persisting at high concentrations for at least 12 months, unlike current approved vaccines. In oncology, preliminary findings from the randomized Phase 2/3 study of our personalized cancer vaccine, GRANITE, in MSS-CRC are rapidly approaching. This is important data not only for Gritstone but for the field, as GRANITE represents an opportunity to bring a new class of therapy to patients with 'cold' solid tumors, for whom the benefits of today's immunotherapies are minimal. The scientific bedrock of GRANITE extends to SLATE, where our collaboration with Steven A. Rosenberg and the NCI is now advancing. With GRANITE and CORAL now in or entering randomized Phase 2 studies, Gritstone stands at the precipice of unlocking the full potential of our novel vaccine platforms in both oncology and infectious diseases."

Corporate Update

- **In August 2023, Gritstone and Genevant Sciences entered into a multi-year option and license agreement that provides Gritstone with nonexclusive access to Genevant's leading LNP technology, on a pathogen-by-pathogen basis, for development and commercialization of Gritstone's samRNA infectious disease vaccines.**

Clinical Program Updates
Tumor-Specific Neoantigen Oncology Programs (GRANITE and SLATE)
GRANITE – Personalized neoantigen vaccine program
SLATE – "Off-the-shelf" neoantigen vaccine program

- **The Phase 2 portion of the Phase 2/3 study evaluating GRANITE as a maintenance therapy in first-line MSS-CRC remains ongoing, and preliminary efficacy data from the Phase 2 portion remain expected in the first quarter of 2024.** Gritstone met its enrollment target of 100 patients randomized in August 2023.
- **The clinical trial collaboration with the National Cancer Institute (NCI) to evaluate an autologous T cell therapy in combination with Gritstone's KRAS-directed "off the shelf" vaccine candidate, SLATE-KRAS, is ongoing. An IND to run a Phase 1 study was cleared by the U.S. Food and Drug Administration (FDA) in October 2023.** The study is led by Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI's Center for Cancer Research. Under the terms of the collaboration, Gritstone will provide the SLATE-KRAS vaccine as requested by NCI. NCI will be responsible for conducting the study at the NIH Clinical Center.
- **Gritstone intends to initiate a randomized Phase 2 clinical trial within SLATE ("off-the-shelf" neoantigen vaccine program) in 2024.**

Infectious Disease Programs
CORAL – Next-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's samRNA platform and novel approach in infectious diseases

- **In September 2023, Gritstone was awarded a contract by BARDA (the Biomedical Advanced Research and Development Authority), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services, to conduct a Phase 2b comparative study evaluating its next-generation vaccine candidate against COVID-19[(a)].** Per the contract, which is valued at up to $433.0 million,

Gritstone is currently preparing to conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of Gritstone's samRNA vaccine candidate against an approved COVID-19 vaccine. Preparations for the study are covered under the initial base period of the contract. Gritstone expects the study to be initiated in the first quarter of 2024.

- **In October 2023, new data was presented from Gritstone's three Phase 1 CORAL studies. Results across these studies highlighted the potential of Gritstone's next-generation samRNA-based approach, which incorporates Spike plus other viral targets ("Spike plus"), to drive broad and long-lasting clinical protection against COVID-19.** Highlights from the data, which were presented at IDWeek 2023, include:
  - High neutralizing antibody (nAb) responses were sustained through the latest evaluable timepoints across all three studies, highlighting potential for durable clinical protection.
    - High nAb levels were demonstrated through at least 12 months in the CORAL-CEPI and CORAL-BOOST studies and at least 6 months in the CORAL-NIH study.
  - T cell responses to Spike plus other viral targets observed in all Phase 1 studies, demonstrating broad and potentially variant-proof immune response.
  - Vaccine candidates were generally well tolerated in all Phase 1 studies; over 300 subjects dosed to date. See all poster presentations here: CORAL-CEPI, CORAL-BOOST, CORAL-NIH

HIV – Collaboration with Gilead under Gilead's HIV Cure Program to research and develop vaccine-based HIV immunotherapy treatment

- **The collaboration with Gilead to research and develop a vaccine-based HIV immunotherapy treatment remains active and ongoing.**

Third Quarter 2023 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were $90.5 million as of September 30, 2023, compared to $185.2 million as of December 31, 2022.
- **Research and development expenses** were $32.8 million for the three months ended September 30, 2023, compared to $26.4 million for the three months ended September 30, 2022. The increase of $6.3 million was primarily due increases of $2.5 million in milestone and license payments, $1.0 million in personnel-related expenses, $2.0 million in facilities-related costs, and $0.9 million in outside services, consisting primarily of clinical trial and other chemistry, manufacturing and controls-related expenses, offset by decreases of $0.1 million in laboratory supplies.
- **General and administrative expenses** were $7.4 million for the three months ended September 30, 2023, compared to $6.5 million for the three months ended September 30, 2022. The increase of $0.9 million was primarily due to increases of $0.5 million in outside services, $0.2 million in personnel-related expenses, and $0.2 million in facilities-related costs.
- **Collaboration, license, and grant revenues** were $1.6 million for the three months ended September 30, 2023, compared to $3.0 million for the three months ended September 30, 2022. During the three months ended September 30, 2023, we recorded $0.1 million in collaboration revenue related to the Gilead collaboration agreement, $0.3 million in collaboration revenue related to the 2seventy agreement, $0.8 million in grant revenue from the CEPI funding agreement, and $0.4 million in grant revenue pursuant to the Gates grant agreement.

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[a]This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00062.

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.

Gritstone Contacts
Investors:
George E. MacDougall
Gritstone bio, Inc.
ir@gritstone.com

Media:
Dan Budwick
1AB
(973) 271-6085
dan@1abmedia.com

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 29,539	$ 55,498
Marketable securities	54,409	116,389
Restricted cash	1,242	3,977
Prepaid expenses and other current assets	5,630	7,014
Total current assets	90,820	182,878
Long-term restricted cash	5,290	5,290
Property and equipment, net	18,952	21,335
Lease right-of-use assets	70,909	17,481
Deposits and other long-term assets	1,246	9,739
Long-term marketable securities	—	4,031
Total assets	$ 187,217	$ 240,754
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,265	$ 8,694
Accrued compensation	7,772	8,215
Accrued liabilities	1,660	4,124
Accrued research and development expenses	2,382	3,343
Lease liabilities, current portion	6,003	5,294
Deferred revenue, current portion	1,301	5,131
Total current liabilities	23,383	34,801
Other liabilities, noncurrent	554	150
Lease liabilities, net of current portion	59,430	15,673
Debt, noncurrent	29,868	19,349
Total liabilities	113,235	69,973
Stockholders' equity:		
Preferred stock	—	—
Common stock	22	22
Additional paid-in capital	702,755	691,910
Accumulated other comprehensive loss	(52)	(80)
Accumulated deficit	(628,743)	(521,071)
Total stockholders' equity	73,982	170,781
Total liabilities and stockholders' equity	$ 187,217	$ 240,754

Gritstone bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration and license revenues	$ 361	$ 436	$ 1,302	$ 7,942
Grant revenues	1,204	2,585	4,659	7,741
Total revenues	1,565	3,021	5,961	15,683
Operating expenses:				
Research and development	32,763	26,436	94,244	81,983
General and administrative	7,406	6,462	20,867	22,209
Total operating expenses	40,169	32,898	115,111	104,192
Loss from operations	(38,604)	(29,877)	(109,150)	(88,509)
Interest income	1,167	462	4,324	663
Interest expense	(991)	(551)	(2,818)	(551)
Other expense	(6)	—	(28)	—
Net loss	(38,434)	(29,966)	(107,672)	(88,397)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	73	129	28	(208)
Comprehensive loss	$ (38,361)	$ (29,837)	$ (107,644)	$ (88,605)
Net loss per share, basic and diluted	$ (0.33)	$ (0.35)	$ (0.94)	$ (1.02)
Weighted-average number of shares used in computing net loss per share, basic and diluted	115,342,613	86,597,405	114,898,379	86,441,212