Gritstone Reports Third Quarter 2022 Financial Results and Provides Business Update

November 3, 2022

-- Two Phase 1 CORAL (SARS-CoV-2) studies deliver positive results, provide further proof-of-concept for application of self-amplifying mRNA (samRNA) as infectious disease vaccine platform --

-- Initial Phase 2 data from KRAS-directed SLATE ("off-the-shelf" neoantigen program) show similar signals in non-small cell lung cancer (NSCLC) as GRANITE (individualized neoantigen program) in colorectal cancer (CRC) --

-- GRANITE randomized Phase 2/3 study in 1L metastatic CRC with registrational intent ongoing; preliminary Phase 2 data expected in 4Q2023 --

-- Cash, cash equivalents, marketable securities and restricted cash of $151.8 million as of September 30, 2022 --

EMERYVILLE, Calif., Nov. 03, 2022 (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, 2022 and reviewed business highlights.

"Gritstone's relentless execution continues to generate novel clinical data," said Andrew Allen, M.D., Ph.D., Co-founder, President and Chief Executive Officer of Gritstone. "The KRAS neoantigen-directed data presented at ESMO 2022 in September, from our off-the-shelf neoantigen program (SLATE), show a molecular response rate of approximately 40%, which was also associated with extended overall survival in advanced lung cancer patients. These results are consistent with prior results from GRANITE in advanced colorectal cancer patients. The scientific foundations of the GRANITE program, common to SLATE, are illuminated in our recent publication of GRANITE Phase 1/2 results in Nature Medicine. This technology platform is establishing its potential to transform the treatment of a large number of solid tumor patients who currently do not respond to checkpoint inhibitors. Through the CORAL program, we continue to demonstrate proof-of-concept for self-amplifying mRNA (samRNA) as a novel, differentiated, scalable, and widely applicable platform technology against COVID-19 and other viral pathogens. As we enter 2023 with a strong balance sheet, our focus remains on driving our clinical programs toward meaningful data catalysts and continuing to unlock the value of our platforms across oncology and infectious diseases."

Clinical Program Updates
Oncology Programs
GRANITE – Individualized neoantigen-directed immunotherapy

- In August 2022, interim results from the Phase 1/2 trial of GRANITE were published in Nature Medicine (here). The paper describes how Gritstone's neoantigen-directed vaccination approach (referred to as "prime-boost") led to both priming and boosting of tumor-specific T cells, with associated molecular responses in approximately half of treated advanced colorectal cancer (CRC) patients. Follow-up data from the Phase 1/2 study have suggested a correlation between molecular response and extended overall survival (MOS of 18+ months among responders vs. 7.8 months in non-responders; latest overall survival results reported in May 2022). These data catalyzed the launch of GRANITE-CRC-1L, a randomized, controlled Phase 2/3 maintenance trial in newly diagnosed metastatic CRC patients that is ongoing and has registrational intent.

- Preliminary data from the Phase 2 portion of GRANITE-CRC-1L are expected in 4Q 2023.

SLATE – "Off-the-shelf" shared neoantigen-directed immunotherapy

- In September 2022, Gritstone presented positive data from a Phase 1/2 study evaluating KRAS-directed SLATE at ESMO. The data included initial results with SLATE-KRAS, a shared mutant KRAS-specific neoantigen vaccine candidate, and updated data using the first version of the vaccine candidate (SLATE v1) which contains both KRAS and non-KRAS neoantigens. In 38 patients with advanced solid tumors, SLATE v1 (n =26) and SLATE-KRAS (n=12) demonstrated a 39% molecular response rate (MRR). In a mature dataset of NSCLC subjects who had progressed on prior chemo-immunotherapy, a positive association was observed between molecular response and overall survival, a signal similar to that seen in the Phase 1/2 study of GRANITE (individualized immunotherapy for advanced solid tumors).

Infectious Disease Programs
CORAL – Second-generation SARS-CoV-2 vaccine program. This program serves as proof-of-concept for Gritstone's infectious disease approach and the potential broad application of samRNA in infectious diseases.

- In October 2022, Gritstone shared interim positive results from the ongoing Phase 1 CORAL-BOOST (NCT05148962) and CORAL-CEPI (NCT05435027) trials at a company-sponsored webinar. Collectively, these results showed Gritstone's samRNA vaccine candidates to be well-tolerated and capable of driving strong, potentially durable and broad immunogenicity across several subject populations and settings.

- In September 2022, enrollment was completed in the CORAL-NIH trial (NCT04776317), which is sponsored and executed by the National Institute of Allergy and Infectious Disease (NIAID).

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, and the Phase 1 clinical study is ongoing.

Corporate Highlights

- In August 2022, Dr. Larry Corey, an internationally renowned expert in virology, immunology and vaccine development and Emeritus President and Director of Fred Hutch, joined Gritstone's Board of Directors.
- In October 2022, Gritstone closed a private investment in public equity financing of $45 million of common stock and pre-funded warrants to support development of its ongoing and future preclinical and clinical programs.

Third Quarter 2022 Financial Results
Cash, cash equivalents, marketable securities and restricted cash were $151.8 million as of September 30, 2022, compared to $223.5 million as of December 31, 2021.

Research and development expenses were $26.4 million for the three months ended September 30, 2022, compared to $24.4 million for the three months ended September 30, 2021. The increase of $2.0 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was primarily due to increases of $1.6 million in personnel-related expenses, $1.0 million in outside services, consisting primarily of clinical trial and other chemistry, manufacturing and controls ("CMC") related expenses, and $0.6 million in facilities-related costs, offset by a decrease of $1.2 million in laboratory supplies.

General and administrative expenses were $6.5 million for the three months ended September 30, 2022, compared to $6.4 million for the three months ended September 30, 2021. The increase of $0.1 million was primarily attributable to an increase of $0.7 million in personnel-related expenses, offset by decreases of $0.4 million in outside services and $0.2 million in facilities-related costs.

Collaboration, license, and grant revenues were $3.0 million for the three months ended September 30, 2022, compared to $2.6 million for the three months ended September 30, 2021. The $0.4 million increase was primarily attributable to revenue recognized under the CEPI Funding Agreement in the amount of $2.1 million, offset by a decrease of $1.4 million related to collaboration revenue recognized under the Gilead Collaboration Agreement.

About Gritstone's Oncology Programs
Gritstone's two clinical stage oncology programs are developing Tumor-Specific Neoantigen (TSNA)-directed vaccine-based immunotherapies that use an adenoviral priming vector and samRNA boost vector ("prime-boost" approach) to deliver relevant neoantigens in combination with immune checkpoint blockade (ICB). GRANITE, which is "individualized" and SLATE, which is "off-the-shelf," aim to induce a substantial neoantigen-specific CD8+ T cell response using neoantigen-containing immunotherapies. GRANITE patients receive a product candidate made specifically for them, based upon their tumor DNA/RNA sequence. In contrast, SLATE patients receive an off-the-shelf product candidate made for common driver mutations present in the patient's tumor as well as the patient having a HLA allele that can present the common driver mutation.

About Gritstone's Infectious Disease Programs
Gritstone's infectious disease programs aim to deliver vaccines that drive durable and broad B cell and T cell immunity to deliver long-lasting clinical protection against viral disease, a clear unmet need in the field. All programs utilize Gritstone's self-amplifying mRNA (samRNA) platform.

About the CORAL Program
Gritstone's CORAL program is evaluating the company's infectious disease approach, which is designed to drive both B cell and T cell immunity using self-amplifying mRNA (samRNA) against SARS-CoV-2. The program currently includes three ongoing Phase 1 trials: CORAL-BOOST, which is evaluating one construct in a boost setting (following primary series of currently-approved COVID-19 vaccines); CORAL-CEPI, which is evaluating multiple constructs in virus-naïve, convalescent, and HIV+ subjects in South Africa; and CORAL-NIH, which is being run by the National Institute of Allergy and Infectious Disease (NIAID) and is evaluating multiple constructs in previously vaccinated healthy volunteers. The program serves as proof-of-concept for the application of Gritstone's platform against coronaviruses and other infectious diseases and is supported by the Bill & Melinda Gates Foundation, NIAID and the Coalition for Epidemic Preparedness Innovations (CEPI).

About Gritstone bio
Gritstone bio, Inc. (Nasdaq: GRTS) is a clinical-stage biotechnology company that aims to create 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 the potential of Gritstone's therapeutic programs; the advancements in Gritstone'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' 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 10, 2022, as well as Gritstone's Quarterly Reports on Form 10-Q filed on May 5, 2022 and August 4, 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 and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Collaboration and license revenues	$ 436	$ 2,401	$ 7,942	$ 44,937
Grant revenues	2,585	213	7,741	213
Total revenues	3,021	2,614	15,683	45,150
Operating expenses:				
Research and development	26,436	24,396	81,983	71,324
General and administrative	6,462	6,373	22,209	19,251
Total operating expenses	32,898	30,769	104,192	90,575
Loss from operations	(29,877)	(28,155)	(88,509)	(45,425)
Interest income	462	37	663	112
Interest expense	(551)	—	(551)	—
Net loss	(29,966)	(28,118)	(88,397)	(45,313)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	129	(7)	(208)	7
Comprehensive loss	$ (29,837)	$ (28,125)	$ (88,605)	$ (45,306)
Net loss per share, basic and diluted	$ (0.35)	$ (0.36)	$ (1.02)	$ (0.59)
Weighted-average number of shares used in computing net loss per share, basic and diluted	86,597,405	77,775,497	86,441,212	76,837,503

Gritstone bio, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share amounts and par value)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 64,909	$ 93,287
Marketable securities	74,900	108,346
Restricted cash	6,727	11,285
Prepaid expenses and other current assets	6,891	7,672
Total current assets	153,427	220,590
Long-term restricted cash	5,290	6,005
Property and equipment, net	21,672	21,622
Lease right-of-use assets	19,321	22,920
Deposits and other long-term assets	5,532	2,352

Long-term marketable securities	—	4,617
Total assets	$ 205,242	$ 278,106
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,885	$ 4,230
Accrued compensation	6,708	6,925
Accrued liabilities	2,670	411
Accrued research and development expenses	5,037	3,706
Lease liabilities, current portion	6,325	7,483
Deferred revenue, current portion	8,688	17,201
Total current liabilities	32,313	39,956
Other liabilities, noncurrent	49	—
Lease liabilities, net of current portion	16,752	18,936
Deferred revenue, net of current portion	—	3,128
Debt, noncurrent	19,281	—
Total liabilities	68,395	62,020
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at September 30, 2022 and December 31, 2021; 73,134,051 and 69,047,878 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	20	20
Additional paid-in capital	626,889	617,523
Accumulated other comprehensive loss	(281)	(73)
Accumulated deficit	(489,781)	(401,384)
Total stockholders' equity	136,847	216,086
Total liabilities and stockholders' equity	$ 205,242	$ 278,106