Gritstone bio Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Updates

March 9, 2023

-- Preliminary data from GRANITE Phase 2/3 study (individualized vaccine for first-line microsatellite-stable colorectal cancer [MSS-CRC]) remain expected in 4Q 2023 --

-- Phase 1/2 efficacy signals from "off-the-shelf" vaccine program (SLATE) consistent with those from GRANITE; randomized study of SLATE in patients with newly-diagnosed metastatic cancer to initiate in 2H 2023 --

-- Clinical evidence building for differentiation of self-amplifying mRNA (samRNA) as a potential next-gen mRNA platform in infectious disease --

-- Cash, cash equivalents, marketable securities, and restricted cash of $185.2 million as of December 31, 2022 --

-- Gritstone to host conference call today at 4:30pm ET --

EMERYVILLE, Calif., March 09, 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 fourth quarter and full year ended December 31, 2022, and provided recent clinical and corporate updates.

"In 2022, we presented positive Phase 1 or 2 data across our GRANITE, SLATE and CORAL vaccine programs, highlighting our ability to generate potent and durable immune responses in both cancer and infectious diseases," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "Of greatest potential importance within our cancer vaccine programs, GRANITE and SLATE, is the consistent association between vaccine-elicited molecular responses in patients with prolonged overall survival. Also of note, we have demonstrated the ability of our therapies to turn "cold" tumors into "hot" ones – even in tough settings such as third line MSS-CRC. The positive results seen in these studies in treatment-refractory disease, coupled with consistent generation of neoantigen-specific cytotoxic T cells, underline the potential of our antigen prediction and heterologous prime-boost vectors (adenovirus and samRNA) to drive clinically important and differentiated immune responses. The clear next step is to move upstream and test the approach in newly diagnosed metastatic cancer patients, and this is well underway in a randomized Phase 2/3 trial with GRANITE in MSS-CRC."

Dr. Allen continued, "In 2023, we have several important milestones, most notably, the preliminary Phase 2 data from our Phase 2/3 GRANITE study in frontline MSS-CRC by year-end. We also plan to initiate a new, randomized Phase 2 trial of a KRAS-directed SLATE in patients with newly-diagnosed metastatic cancer in the second half of the year. We are highly encouraged by the data from our GRANITE program to date and believe success with our Phase 2/3 GRANITE study would support expanded evaluation across both cold and hot tumors and into different treatment settings including adjuvant therapy. This is an important year for personalized cancer vaccines, with multiple companies reporting randomized trial data, and a positive outcome in our trial in metastatic CRC, a clearly "cold" tumor, would be of huge significance, potentially opening the door for the majority of solid tumor patients to derive benefit from immunotherapy for the first time. Fueled by the extended survival and promising patient outcomes observed in our Phase 1/2 in advanced CRC, which are published in Nature Medicine, we confidently await our randomized Phase 2 data late this year."

Clinical Program Updates
Tumor-Specific Neoantigen (TSNA) Oncology Programs
GRANITE – Individualized, TSNA-directed vaccine-based immunotherapy
SLATE – "Off-the-shelf" shared TSNA-directed vaccine-based immunotherapy

- **Preliminary data from the randomized Phase 2/3 study evaluating GRANITE (individualized neoantigen vaccine for microsatellite-stable colorectal cancer [MSS-CRC]) remain expected in 4Q 2023.**
  -- Enrollment of the Phase 2 portion of study, designed to evaluate the individualized neoantigen vaccine as a maintenance therapy in eighty patients with first-line MSS-CRC, is ongoing.

  -- The company remains on track to report preliminary data from the Phase 2 portion of the study, molecular response (circulating tumor DNA [ctDNA]) and progression-free survival data [evaluated by both RECIST and iRECIST criteria] on patients completing at least 4 months of treatment, in 4Q 2023.

- **Positive results from Phase 1/2 studies of GRANITE and SLATE reinforce association between molecular response (reduction in ctDNA level) and extended overall survival.**

  GRANITE
  -- In August 2022, interim results from the Phase 1/2 trial of GRANITE, Gritstone's individualized neoantigen vaccine for solid tumor cancers, were published in Nature Medicine (here). The paper describes how Gritstone's neoantigen-directed dual vaccination approach (referred to as "prime-boost") led to both priming and boosting of tumor-specific cytotoxic T cells, with associated molecular responses in approximately half of treated advanced colorectal cancer

(CRC) patients.

-- In November 2022, Gritstone announced the median overall survival (mOS) among molecular responders living with third line MSS-CRC (a subset within the Phase 1/2 study of GRANITE) will exceed 22 months; median not yet reached (here). This compares to mOS of 7.8 months in evaluable MSS-CRC patients in the study who did not exhibit a molecular response, and mOS of 6-7 months observed in pivotal studies of FDA-approved therapeutics in this context (trifluridine/tipiracil combination and regorafenib monotherapy). Molecular response rate (MRR) among evaluable MSS-CRC patients was 55% (6/11).

SLATE
-- In September 2022, initial results shared at ESMO from Phase 1/2 study of KRAS-directed SLATE demonstrated similar molecular response rate and overall survival trend (here). In 38 patients with advanced solid tumors (largely MSS-CRC and NSCLC), SLATE v1 (n =26) and SLATE-KRAS (n=12) demonstrated a 39% MRR in evaluable patients with MSS-CRC and NSCLC. In 18 patients with NSCLC, all of whom had progress on prior (chemo)immunotherapy, a molecular response was correlated with extended OS. NSCLC patients with a molecular response demonstrated a median OS (9.6 months) more than double of those without a molecular response (4.5 months).

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

- **Phase 1 CORAL studies continue, with enrollment in CORAL-CEPI trial (n = 341) now complete. Additional data from the CORAL-BOOST and CORAL-CEPI trials, which aim to further characterize and demonstrate the potential utility of self-amplifying mRNA (samRNA), are expected in 2Q2023.**
  -- In August 2022, Gritstone reported 6-month neutralizing antibody data from the first two cohorts of its CORAL-BOOST trial. Results showed in all observable patients, the strong neutralizing antibody responses originally reported in January 2022 persisted without decay after 6 months (here).

  -- In October 2022, Gritstone shared interim positive results from the ongoing Phase 1 CORAL-BOOST and CORAL-CEPI studies 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.

  -- Enrollment in the CORAL-NIH trial completed in 2022. This study 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.

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

Recent Corporate Updates

- **In October 2022, Gritstone raised $45 million through a private investment in public equity financing** to support development of its ongoing and future pre-clinical and clinical programs.

- **In February 2023, Gritstone announced a clinical trial agreement with the National Cancer Institute (NCI)** to evaluate an autologous T cell therapy expressing a T cell receptor targeting mutated KRAS in combination with Gritstone's KRAS-directed vaccine candidate, SLATE-KRAS, in a Phase 1 study led by Steven A. Rosenberg, M.D., Ph.D.

- **In February 2023, results from a preclinical study conducted in collaboration with Gilead Sciences were presented at Conference on Retroviruses and Opportunistic Infections (CROI) 2023.** The first data disclosed from the Gritstone-Gilead HIV Cure collaboration, results showed that simian immunodeficiency virus (SIV) Chimpanzee Adenovirus (ChAd) and self-amplifying mRNA (samRNA) vaccines induced a strong and broad CD8+ T cell immune response, which was significantly enhanced in combination with immune modulators.

Intellectual Property Update
Gritstone's IP estate includes issued patents related to its processes and technologies, including Gritstone EDGE™, the company's novel epitope discovery platform used in neoantigen prediction for its personalized cancer vaccines.

- In December 2022, Gritstone announced the United States Patent and Trademark Office (USPTO) issued two new patents related to the company's novel self-amplifying mRNA (samRNA) vaccine platform technology (U.S. Patent No. 11,504,421

and U.S. Patent No. 11,510,973).

- In February 2023, the USPTO issued a separate patent (U.S. Patent No. 11,264,117) directed to Gritstone's proprietary ChAd vector, which is modified to improve viral production.

Full Year 2022 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were $185.2 million as of December 31, 2022, compared to $223.5 million as of December 31, 2021.

- **Research and development expenses** were $111.4 million for the year ended December 31, 2022 compared to $97.5 million for the year ended December 31, 2021. The increase was primarily due to increases in personnel-related costs and clinical trial expenses.

- **General and administrative expenses** were $29.0 million for the year ended December 31, 2022 compared to $25.9 million for the year ended December 31, 2021. The increase was primarily attributable to an increase in personnel-related costs and an increase in outside services for legal, finance, recruiting and other professional services to support our ongoing operations.

- **Collaboration, license, and grant revenues** were $19.9 million for the year ended December 31, 2022, compared to $48.2 million for the prior year. During the year ended December 31, 2022, we recorded $1.6 million in collaboration revenue related to the Gilead Collaboration Agreement, and $7.7 million in collaboration revenue related to the 2seventy bio Agreement. During the year ended December 31, 2022, we recorded $9.5 million in grant revenue related to the CEPI Agreement and $1.2 million in grant revenue related to the Gates Agreement.

Conference Call and Webcast Details
A conference call and webcast to discuss fourth quarter and full year 2022 results will be held at 4:30pm ET today (March 9):

Conference call: 1-877-407-4018
Conference ID: 13734754
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1586967&tp_key=44c4441022

An archived replay will be accessible at https://ir.gritstonebio.com/investors/events for 30 days following the event.

About Gritstone bio
Gritstone is working 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 and have programs in viral diseases and solid tumors. Independently and with our partners, we are advancing a portfolio of product candidates with the aim 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 9, 2023 and any current and periodic reports filed with the Securities and Exchange Commission.

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 55,498	$ 93,287
Marketable securities	116,389	108,346
Restricted cash	3,977	11,285
Prepaid expenses and other current assets	7,014	7,672
Total current assets	182,878	220,590
Long-term restricted cash	5,290	6,005
Property and equipment, net	21,335	21,622
Lease right-of-use assets	17,481	22,920
Deposits and other long-term assets	9,739	2,352
Long-term marketable securities	4,031	4,617
Total assets	$ 240,754	$ 278,106
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,694	$ 4,230
Accrued compensation	8,215	6,925
Accrued liabilities	4,124	411
Accrued research and development expenses	3,343	3,706
Lease liabilities, current portion	5,294	7,483
Deferred revenue, current portion	5,131	17,201
Total current liabilities	34,801	39,956
Other liabilities, noncurrent	150	—
Lease liabilities, net of current portion	15,673	18,936
Deferred revenue, net of current portion	—	3,128
Debt, noncurrent	19,349	—
Total liabilities	69,973	62,020
Stockholders' equity:		
Common stock	22	20
Additional paid-in capital	691,910	617,523
Accumulated other comprehensive loss	(80)	(73)
Accumulated deficit	(521,071)	(401,384)
Total stockholders' equity	170,781	216,086
Total liabilities and stockholders' equity	$ 240,754	$ 278,106

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

	Year ended December 31,	
	2022	2021
Revenues:		
Collaboration and license revenues	$ 9,269	$ 46,717
Grant revenues	10,676	1,497
Total revenues	19,945	48,214
Operating expenses:		
Research and development	111,403	97,490
General and administrative	28,970	25,933
Total operating expenses	140,373	123,423
Loss from operations	(120,428)	(75,209)
Interest income	1,976	164
Interest expense	(1,235)	(37)
Net loss	(119,687)	(75,082)
Other comprehensive loss:		
Unrealized loss on marketable securities	(7)	(73)
Comprehensive loss	$ (119,694)	$ (75,155)
Net loss per share, basic and diluted	$ (1.32)	$ (0.95)
Weighted-average number of shares used in computing net loss per share, basic and diluted	90,918,333	78,885,186


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