Gritstone Reports Fourth Quarter 2021 and Full Year 2021 Financial Results and Provides Corporate Updates

March 10, 2022

-- Four trials now initiated for CORAL, Gritstone's second-generation COVID-19 program focused on delivering T cell enhanced self-amplifying mRNA (samRNA) vaccines --

-- Oncology programs advancing as planned, with individualized neoantigen-based immunotherapy, GRANITE, now in a Phase 2/3 trial in newly diagnosed metastatic, microsatellite-stable colorectal cancer (MSS-CRC) patients and a Phase 2 trial of mutant KRAS-focused "off the shelf" neoantigen-based immunotherapy SLATE ongoing --

-- Cash, cash equivalents, marketable securities and restricted cash of $223.5 million as of December 31, 2021 --

EMERYVILLE, Calif., March 10, 2022 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing the next generation of cancer and infectious disease immunotherapies, today reported financial results for the fourth quarter and full year ended December 31, 2021 and provided recent clinical and corporate updates.

"2021 was a transformational year for Gritstone, as we extended our unique understanding of T cell antigens and proprietary vaccine delivery platforms to infectious disease, expanding our pipeline to include novel programs in COVID-19 (CORAL) and human immunodeficiency virus (HIV). Furthermore, we made significant progress with our tumor-specific neoantigen oncology programs, GRANITE and SLATE, which are advancing into later-stage trials," said Andrew Allen, M.D., Ph.D., Co-Founder, President and Chief Executive Officer of Gritstone. "In CORAL, we have demonstrated the potential for our T cell enhanced samRNA vaccine candidates to drive broad and durable immune responses in humans against both current and future variants against COVID-19, a credible first step toward developing a pan-coronavirus vaccine given the high conservation of many T cell antigens across different coronaviruses. Within oncology, we have continued to demonstrate the ability to drive a large and sustained T cell response, including the challenging CD8+ killer T cells, against tumor-specific neoantigens. These T cell responses are potentially driving the molecular and radiological responses observed in our "off the shelf" program, SLATE, which is focused on KRAS mutations, and also appear to be driving molecular response and extended overall survival in the end-stage colorectal cancer patients treated in our individualized program, GRANITE."

"Our collective experience with cancer immunotherapy suggests that as these programs move into earlier stages of disease, immune responses may be stronger and the potential benefits of our approach will be further accentuated," Dr. Allen continued. "Consequently, we are excited to have initiated randomized Phase 2/3 trials with GRANITE in colorectal cancer (CRC) patients where unmet need persists and checkpoint inhibitor therapy has had little impact to date in the vast majority of patients. We believe Gritstone is well-positioned to continue advancing our programs and platforms, and look forward to sharing updates as the year progresses."

Clinical Program Updates

Tumor-Specific Neoantigen (TSNA) Oncology Programs

GRANITE – Individualized, tumor specific neoantigen (TSNA)-directed immunotherapy using an adenoviral priming vector and self-amplifying mRNA boost vector to deliver relevant neoantigens

- To date, an ongoing Phase 1/2 study assessing GRANITE in combination with an anti-PD-1 checkpoint inhibitor, nivolumab, and subcutaneous anti-CTLA-4 antibody, ipilimumab, has demonstrated a favorable safety and tolerability profile for patients treated in the study and demonstrated consistent induction of neoantigen-specific CD8+ T cells, and reduction in circulating tumor DNA (ctDNA), an increasingly recognized biomarker within utility in immunotherapy in advanced solid tumors.

- Additionally, colorectal cancer patients who demonstrated a molecular response (ctDNA reduction >50% from baseline) had median overall survival of >17 months (median not reached) whereas those without molecular response exhibited a median overall survival of 7.8 months, the latter being consistent with expected outcome in 3rd line treatment of metastatic, microsatellite-stable colorectal cancer (MSS-CRC) patients. These data support the potential for GRANITE to offer benefit in a disease setting such as MSS-CRC where patients do not traditionally respond to checkpoint inhibitor therapy.

- Given the results of the Phase 1/2 study, Gritstone has initiated two studies assessing GRANITE in earlier stages of disease: GRANITE-CRC-1L (a Phase 2/3 randomized, controlled trial evaluating the individualized neoantigen vaccine GRANITE in combination with immune checkpoint blockade for the first line (1L) maintenance treatment of newly diagnosed patients with metastatic MSS-CRC) and GRANITE-CRC-ADJUVANT (Randomized, controlled phase 2 trial of adjuvant GRANITE immunotherapy in high risk MSS-CRC patients with stage II/III disease who are ctDNA+ after definitive surgery). In January 2022, Gritstone announced the first patient was enrolled for inclusion in the GRANITE-CRC-1L trial. As of March 2022, the first patient was enrolled for inclusion in the GRANITE–CRC-ADJUVANT study.

SLATE – "Off-the-shelf" shared neoantigen-directed immunotherapy using an adenoviral priming vector and self-amplifying mRNA boost vector to deliver a cassette of shared TSNA

- Preliminary data from an ongoing Phase 1/2 trial in advanced disease patients indicated a favorable safety and tolerability profile and induction of CD8+ T cells against multiple KRAS TP53 driver mutations. Clinical activity was observed in NSCLC patients who had all progressed on prior chemoimmunotherapy, including 6 NSCLC patients with the G12C KRAS mutation. Among these G12C patients, ctDNA responses were observed in 2 of 3 eligible for analysis, which correlated with clinical benefit, and a RECIST radiologic response (unconfirmed) was observed in one 2nd line patient with aggressive disease who had progressed after 3 months of 1st line chemo-immunotherapy. There were no safety signals of note; the most common adverse events being low grade, self-limiting fever and injection site reactions. An optimized SLATE cassette (SLATE-KRAS, v2), which exclusively includes $KRAS^{mut}$ epitopes, exhibited immunogenic superiority over version 1 in preclinical studies. This next-generation SLATE-KRAS cassette is now in Phase 2 testing in patients with advanced non-small cell lung cancer (NSCLC) and CRC, and initial data are expected in 2H 2022.

Infectious Disease Programs

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.

- To date, the CORAL program has demonstrated positive preclinical and clinical data supporting the approach of a T cell enhanced samRNA vaccine against COVID-19, indicating a favorable safety profile and induction of both neutralizing antibodies and T cells.

- In January 2022, Gritstone announced positive clinical data from the first cohort of CORAL-BOOST, a Phase 1 study evaluating the safety, reactogenicity, and immunogenicity of a samRNA vaccine directed against Spike and highly conserved non-Spike TCEs as a booster against SARS-CoV-2 in healthy adults ≥60 years who previously received two doses of AstraZeneca's first-generation COVID-19 vaccine AZD1222 (Vaxzevria). Enrollment of the second cohort of CORAL-BOOST has since concluded and based on the favorable immunogenicity and reactogenicity seen with the 10µg dose, the study is proceeding to additional cohorts utilizing this dose.

- Two additional Phase 1 trials, CORAL-CEPI and CORAL-IMMUNOCOMPROMISED, were initiated in 1Q 2022. The CORAL-CEPI trial, which is evaluating T cell enhanced omicron- and beta-spike constructs in virus-naïve, convalescent, and HIV+ patients, is being run in South Africa with support from the Coalition for Epidemic Preparedness Innovations (CEPI). The CORAL-IMMUNOCOMPROMISED trial, which is evaluating T cell enhanced samRNA and chimpanzee adenovirus (ChAd) vaccines in B cell deficient subjects, is being run in the United Kingdom.

- CORAL-NIH, a Phase 1 study evaluating the immunogenicity and safety of samRNA and/or ChAd vaccines in healthy adult subjects that is supported by the National Institute of Allergy and Infectious Diseases (NIAID) is being conducted through their Infectious Diseases Clinical Research Consortium (IDCRC). Initial data is expected in 1H 2022.

- All four clinical trials within the CORAL program are now enrolling and Gritstone expects to provide data updates on each of these trials throughout the remainder of 2022.

HIV – Collaboration with Gilead Sciences, Inc (Gilead) under their HIV Cure Program to research and develop vaccine-based HIV immunotherapy treatment

- Following initiation of the collaboration with Gilead in early 2021, an IND was submitted and subsequently cleared in December 2021.

2021 Funding Highlights and Recent Corporate Updates

2021 Funding Highlights

- Gritstone entered into a funding agreement of up to $20.6 million with the Coalition for Epidemic Preparedness Innovations (CEPI) to advance the clinical development of Gritstone's CORAL second generation mRNA COVID-19 vaccine program.
- Gritstone secured $55 million Private Placement led by Frazier Life Sciences Public Fund, Redmile Group and Gilead Sciences.
- Gritstone secured $60 million payment from Gilead at closing of HIV program collaboration, consisting of a $30 million upfront cash payment and a $30 million equity investment at a premium.

Recent corporate updates

- The funding agreement with CEPI was expanded for up to $5 million to advance the clinical development of Gritstone's

CORAL second generation mRNA COVID-19 vaccine program targeting the omicron variant in South Africa (December 2021).
- Clare Fisher, Senior Vice President of Business Development and Mergers & Acquisitions at BeiGene, was appointed to the Gritstone Board of Directors effective as of January 1, 2022 (December 2021).
- Gritstone was added to the Nasdaq Biotechnology Index (December 2021).

Full Year 2021 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were $223.5 million as of December 31, 2021, compared to $172.1 million as of December 31, 2020.

- **Research and development expenses** were $97.5 million for the year ended December 31, 2021, compared to $88.6 as of December 31, 2020. The increase was primarily due to increases in personnel-related expenses and clinical trial expenses.

- **General and administrative expenses** were $25.9 million for the year ended December 31, 2021, compared to $21.4 million as of December 31, 2020. The increase was primarily attributable to an increase in personnel-related costs as we expanded our headcount, and an increase in outside services for legal, finance, recruiting and other professional services to support our ongoing operations and operate as a public company.
- **Collaboration and license revenue** was $46.7 million for the year ended December 31, 2021, compared to $3.5 million for the prior year. During the year ended December 31, 2021, we recorded $38.6 million in license revenue and $5.1 million in collaboration revenue related to the Gilead Collaboration Agreement, and $3.0 million in collaboration revenue related to the 2seventy bio Agreement.

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 artificial intelligence-based platform, Gritstone EDGE^{TM}, 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 program delivering T cell enhanced self-amplifying mRNA (samRNA) vaccines for COVID-19 that is supported by departments within the National Institutes of Health (NIH), the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI) and through 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 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' 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 Gritstone in general, see Gritstone's most recent Annual Report on Form 10-K filed on March 10, 2022 and Gritstone's future reports to be filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Gritstone as of the date hereof. Gritstone disclaims any obligation to update any forward-looking statements, except as required by law.

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

(In thousands, except share and per share amounts)

	Twelve Months Ended December 31,		
	2021	**2020**	**2019**
Collaboration revenue	$ 46,717	$ 3,462	$ 4,365
Grant revenue	1,497	575	-
Total revenues	48,214	4,037	4,365
Operating expenses:			
Research and development	97,490	88,643	82,896
General and administrative	25,933	21,411	19,409
Total operating expenses	123,423	110,054	102,305
Loss from operations	(75,209)	(106,017)	(97,940)
Interest income, net	127	703	3,507
Net loss	$ (75,082)	$ (105,314)	$ (94,433)
Net loss per common share, basic and diluted	$ (0.95)	$ (2.79)	$ (2.81)
Shares used to compute for net loss per common share, basic and diluted	78,885,186	37,792,365	33,554,823

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

	December 31, 2021	**December 31, 2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 93,287	$ 170,056
Marketable securities	108,346	1,002
Restricted cash	11,285	-
Prepaid expenses and other current assets	7,672	4,332
Total current assets	220,590	175,390
Restricted cash	6,005	992
Property and equipment, net	21,622	22,105
Operating lease right-of-use assets	22,920	21,344
Deposits and other long-term assets	2,352	1,736
Long-term marketable securities	4,617	-
Total assets	$ 278,106	$ 221,567
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,230	$ 9,578
Accrued compensation	6,925	6,331
Accrued liabilities	411	677
Accrued research and development	3,706	1,053
Lease liabilities, current portion	7,483	5,874
Deferred revenue, current portion	17,201	3,475
Total current liabilities	39,956	26,988
Other non-current liabilities	-	395
Lease liabilities, net of current portion	18,936	19,225
Deferred revenue, net of current portion	3,128	8,220
Total liabilities	62,020	54,828
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	20	18
Additional paid-in capital	617,523	493,023
Accumulated other comprehensive gain	(73)	-

Accumulated deficit	(401,384)	(326,302)
Total stockholders' equity	216,086	166,739
Total liabilities and stockholders' equity	$ 278,106	$ 221,567