



## Gritstone Reports Third Quarter 2021 Financial Results and Business Update

November 3, 2021

- Phase 1 data from Gritstone-sponsored CORAL study (SARS-CoV-2 second generation vaccine utilizing self-amplifying mRNA boost) expected in early Q1 2022; CORAL is a multi-trial vaccine program which seeks to drive broad and durable immune responses to SARS-CoV-2 variants
- Data presented during ESMO 2021 show robust clinical and molecular responses and favorable safety profile across difficult to treat solid tumors with GRANITE (individualized neoantigen program) and SLATE (off-the-shelf shared neoantigen program)
- Cash, cash equivalents, marketable securities and restricted cash of \$216.4 million as of September 30, 2021

EMERYVILLE, Calif., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, today reported financial results for the third quarter ended September 30, 2021 and reviewed business highlights.

"We are pleased with our strengthened cash position and the significant clinical progress achieved during this third quarter," said Andrew Allen, M.D., Ph.D., Co-Founder, President and Chief Executive Officer of Gritstone. "Our leadership in neoantigen-derived immunotherapy and vaccination strategies for cancer and infectious diseases has been validated by several key partnerships and was further supported by a \$55 million dollar PIPE financing led by Frazier Life Sciences Public Fund, enabling the rapid clinical development of our second-generation mRNA and integrated vaccine manufacturing capabilities. The data generated to date using both heterologous and homologous prime-boost approaches with our two vectors further validate the vast potential of our platform to deliver broad and durable immune responses across infectious diseases and common, solid cancers. We look forward to upcoming CORAL milestones, including imminent non-human primate viral challenge data from our collaboration with NIAID and Phase 1 data from our company-sponsored trial evaluating CORAL as a boost and immunogenicity enhancer for first-generation COVID-19 vaccines in older adults early in the first quarter of 2022."

### Corporate Highlights

- 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, including a clinical trial in South Africa and manufacturing optimization ([CEPI Press Release, August 2021](#))
- Received gross proceeds of **\$55.0 million from a private investment in public equity (PIPE)** financing led by Frazier Life Sciences Public Fund, with additional participation from Redmile Group and Gilead Sciences ([PIPE Press Release, September 2021](#))

### Clinical Highlights and Updates

#### Tumor-Specific Neoantigen (TSNA) Oncology Programs

*GRANITE – Individualized, TSNA-directed immunotherapy using an adenoviral priming vector and self-amplifying mRNA boost vector*

- Updated Phase 1/2 results evaluating the safety, immunogenicity and clinical activity of GRANITE individualized neoantigen immunotherapy in combination with PD-1 checkpoint inhibitor nivolumab and subcutaneous anti-CTLA-4 antibody ipilimumab in advanced solid tumors presented at ESMO 2021 ([GRANITE Press Release, September 2021](#))
- GRANITE immunotherapy demonstrated a 44% molecular response rate (4/9) as measured by >50% reduction in circulating tumor DNA (ctDNA) with associated median overall survival >17 months in patients with end-stage microsatellite-stable colorectal cancer (MSS-CRC) for whom median overall survival is typically 6-7 months (as observed in the 5/9 patients without molecular response)
- A Phase 2/3 randomized, controlled trial of maintenance GRANITE immunotherapy in newly diagnosed metastatic, MSS-CRC patients is expected to initiate in the first quarter of 2022
  - This Phase 2/3 trial has registrational intent and has been discussed with the FDA
- A Phase 2 randomized trial of adjuvant GRANITE immunotherapy in MSS-CRC patients with stage II/III disease who are ctDNA+ after definitive surgery is expected to initiate in the second quarter of 2022

*SLATE – "Off-the-shelf" shared neoantigen-directed immunotherapy using an adenoviral priming vector and self-amplifying mRNA boost vector*

- Presented Phase 1/2 data demonstrating SLATE v1 + nivolumab + ipilimumab in 26 patients with metastatic solid tumors
- Observed multiple molecular responses and an unconfirmed RECIST radiologic response were observed in patients with metastatic NSCLC, all of whom had progressed on prior (chemo)immunotherapy ([SLATE Press Release, September 2021](#))

- SLATE v2, a mutant KRAS-focused version optimized for increased immune response, is currently being evaluated in a Phase 2 trial in patients with NSCLC and MSS-CRC. Initial clinical data are anticipated by mid-2022.

### Infectious Disease Programs

*CORAL – second-generation SARS-CoV-2 vaccine program delivering both spike and highly conserved non-spike T cell epitopes within either a self-amplifying mRNA vector or an optimized chimpanzee adenoviral vector (ChAdV). This approach offers potential for more durable clinical protection and broader immunity against SARS-CoV-2 variants than 1<sup>st</sup> generation products by inducing potent CD8+ T cells in addition to neutralizing antibody responses*

- Dosed first volunteer in a company-sponsored Phase 1 trial evaluating GRT-R910, a self-amplifying mRNA (SAM) second generation SARS-CoV-2 vaccine designed to boost and expand the immunogenicity of first-generation COVID-19 vaccines in subjects 60 years of age or older. ([GRT-R910 Press Release, September 2021](#))
  - Initial Phase 1 data from this study are expected early in the first quarter 2022
- Our collaboration with the National Institute of Allergy and Infectious Disease (NIAID) to evaluate the safety, tolerability and immunogenicity of investigational ChAdV and SAM SARS-CoV-2 vaccines continues:
  - Non-human primate viral challenge data are expected in November 2021
  - Preliminary results from a Phase 1 trial are now expected in the first half of 2022 due to protocol amendments necessitated by the changing landscape of vaccine use in the United States

### Third Quarter 2021 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were \$216.4 million as of September 30, 2021 compared to \$172.1 million as of December 31, 2020.
- **Research and development expenses** were \$24.4 million for the three months ended September 30, 2021, compared to \$22.1 million for the three months ended September 30, 2020. The increase was primarily due to increases of \$1.7 million in personnel-related expenses and \$2.4 million in outside services, offset by \$1.8 million decreases in laboratory supplies.
- **General and administrative expenses** were \$6.4 million for the three months ended September 30, 2021, compared to \$5.0 million for the three months ended September 30, 2020. The increase was primarily attributable to increases in personnel-related expenses and outside services.
- **Collaboration revenue** was \$2.4 million for the three months ended September 30, 2021, compared to \$0.8 million for the three months ended September 30, 2020. The increase was due to the collaboration revenue associated with the collaboration agreement with Gilead from January 2021.

### 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 machine learning-based platform, Gritstone EDGE™, 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 second generation COVID-19 vaccine program, with support from the National Institute of Allergy and Infectious Disease (NIAID), the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI) and through a license agreement with La Jolla Institute for Immunology (LJI). Additionally, the company has a global collaboration for the development of a therapeutic HIV vaccine with Gilead Sciences. For more information, please visit [gritstone.com](http://gritstone.com).

### Gritstone Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to Gritstone bio, Inc.'s ("Gritstone", "we" or "our") preclinical and clinical product candidates, including GRANITE, SLATE, CORAL, and HIV programs; the advancements in our 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. Forward-looking statements generally contain words such as "believes," "expects," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," "anticipates," and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters. 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 November 3, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.

**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	\$ 2,401	\$ 795	\$ 44,937	\$ 2,544
Grant revenue	213	144	213	144
Total revenues	2,614	939	45,150	2,688
Operating expenses:				
Research and development	24,396	22,050	71,324	65,807
General and administrative	6,373	5,031	19,251	15,751
Total operating expenses	30,769	27,081	90,575	81,558
Loss from operations	(28,155)	(26,142)	(45,425)	(78,870)
Interest income, net	37	69	112	723
Net loss	\$ (28,118)	\$ (26,073)	\$ (45,313)	\$ (78,147)
Net loss per common share, basic and diluted	\$ (0.36)	\$ (0.69)	\$ (0.59)	\$ (2.10)
Shares used to compute for net loss per common share, basic and diluted	77,775,479	37,750,145	76,837,503	37,268,318

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

	September 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 131,423	\$ 170,056
Marketable securities	68,255	1,002
Restricted cash	10,995	-
Prepaid expenses and other current assets	7,728	4,332
Total current assets	218,401	175,390
Restricted cash	5,687	992
Property and equipment, net	21,337	22,105
Operating lease right-of-use assets	23,793	21,344
Deposits and other long-term assets	2,064	1,736
Total assets	\$ 271,282	\$ 221,567
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,393	\$ 9,578
Accrued compensation	6,115	6,331
Accrued liabilities	3,022	677
Accrued research and development	2,540	1,053
Lease liabilities, current portion	7,458	5,874
Deferred revenue, current portion	13,786	3,475
Total current liabilities	36,314	26,988
Other non-current liabilities	395	395
Lease liabilities, net of current portion	19,844	19,225
Deferred revenue, net of current portion	6,774	8,220

Total liabilities	63,327	54,828
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	20	18
Additional paid-in capital	579,543	493,023
Accumulated other comprehensive gain	7	-
Accumulated deficit	(371,615)	(326,302)
Total stockholders' equity	207,955	166,739
Total liabilities and stockholders' equity	\$ 271,282	\$ 221,567

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