



Gritstone Reports Second Quarter 2021 Financial Results and Business Update

August 5, 2021

- *GRANITE Phase 1/2 data of individualized neoantigen immunotherapy in advanced solid tumors accepted for mini- oral presentation at ESMO 2021*
- *Gritstone-sponsored CORAL (second-generation SARS-CoV-2 vaccine) studies to launch before year-end in select populations*
- *Cash, cash equivalents, marketable securities and restricted cash of \$176.2 million as of June 30, 2021*

EMERYVILLE, Calif., Aug. 05, 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 second quarter ended June 30, 2021 and reviewed business highlights.

"The Gritstone team has made significant progress across both our clinical-stage oncology and infectious disease programs using our proprietary Gritstone EDGE™ and antigen delivery platforms," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. "We are excited to present a comprehensive data update in September from our Phase 1/2 GRANITE program, building upon our previously demonstrated ability to drive strong, consistent CD8+ T cell responses against neoantigens in patients with end-stage solid tumors, together with early signs of clinical benefit. We now have longer-term follow-up data plus new patient data that address the key question of whether these robust CD8+ T cell responses confer clinical benefit in challenging, end-stage patients."

Dr. Allen continued, "Our work to develop a second-generation vaccine that offers the potential for robust durability and broader immunity against SARS-CoV-2 advances with the initiation of our own clinical studies evaluating CORAL as a boost to EUA vaccines, or as a vaccine for immunocompromised individuals, who mount poor antibody responses to the existing vaccines. Our COVID vaccines are directed against the spike protein but also include high quality T-cell antigens from other regions of the viral genome, offering the potential to address resistant spike mutants which continue to emerge. We look forward to validating our novel approach in these studies and in the NIAID sponsored trial, which is expected to generate data before year end."

Corporate Highlights

- Gritstone appointed two new members to its Executive Team:
 - Celia Economides was appointed as executive vice president and chief financial officer. Her leadership experience spans 20 years in roles across business and finance strategy, investor and corporate communications, medical affairs, and business analytics.
 - Stacy Proctor, a 20-year veteran with experience across several diverse industries with global and multiple worksites, was appointed as senior vice president and head of people.

Clinical Highlights and Updates

Tumor-Specific Neoantigen (TSNA) Oncology Programs

GRANITE – Individualized, TSNA-directed immunotherapy

- Enrollment is complete in the Phase 2 expansion cohorts of the Phase 1/2 trial evaluating GRANITE as a late-line therapy for metastatic microsatellite stable colorectal cancer (MSS-CRC), gastroesophageal (GEA) cancer and non-small cell lung cancer (NSCLC).
 - Phase 1/2 results will be presented as part of a mini-oral presentation during the European Society of Medical Oncology (ESMO 2021) taking place virtually from September 16-21, 2021.
- Two randomized Phase 2 trials evaluating GRANITE in MSS-CRC patients at earlier disease stages are expected to initiate in the first half of 2022.

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

- Enrollment and treatment are complete in the Phase 2 portion of SLATE Version (v)1 evaluating shared neoantigen directed therapy in combination with immune checkpoint blockade for patients with advanced solid tumors including those with certain KRAS mutations.

- A data update will be provided in the third quarter of 2021.
- Gritstone received clearance for its investigational new drug application (IND) for SLATE v2 targeting select KRAS-mutant solid tumors.
- Gritstone intends to submit an IND for SLATE v3 targeting an unnamed shared neoantigen before the end of 2021.

Infectious Disease Programs

CORAL – second-generation SARS-CoV-2 vaccine containing spike and other SARS-CoV-2 T cell epitopes offering the potential for more durable protection and broader immunity against SARS-CoV-2 variants

- The National Institute of Allergy and Infectious Disease (NIAID) - sponsored Phase 1 clinical trial evaluating CORAL expanded to include cohorts of volunteers who have received first generation COVID-19 vaccines under Emergency Use Authorization (EUA).
 - Preliminary results from this trial are expected before the end of 2021.
- Gritstone is on track to begin its company-sponsored clinical studies evaluating CORAL as a boost to EUA vaccines and for vaccination of immunocompromised individuals, in the third and fourth quarters of 2021, respectively.

HIV – HIV-specific therapeutic vaccine using Gritstone's proprietary prime-boost vaccine platform, comprised of self-amplifying mRNA (SAM) and adenoviral vectors, with antigens developed by Gilead.

- Gritstone established a collaboration with Gilead Sciences (Gilead) in Q1 2021, whereby the company received \$60 million in proceeds, to develop a vaccine-based immunotherapy as part of Gilead's efforts to find a curative treatment for human immunodeficiency virus (HIV) infection. The collaboration continues to remain on track.

Second Quarter 2021 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were \$176.2 million as of June 30, 2021 compared to \$172.1 million as of December 31, 2020.
- **Research and development expenses** were \$22.1 million for the three months ended June 30, 2021, compared to \$21.3 million for the three months ended June 30, 2020. The increase was primarily due to increases of \$1.5 million in personnel-related expenses and outside services, offset by \$0.7 million decreases in facility costs and laboratory supplies.
- **General and administrative expenses** were \$5.9 million for the three months ended June 30, 2021, compared to \$5.2 million for the three months ended June 30, 2020. The increase was primarily attributable to increases in outside services.
- **Collaboration and license revenues** were \$2.8 million for the three months ended June 30, 2021, compared to \$0.5 million for the three months ended June 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 COVID-19 program to develop a second-generation vaccine, with support from departments within the National Institutes of Health (NIH), the Bill & Melinda Gates Foundation, 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 gritstone.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 the company'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 the company in general, see Gritstone's most recent Quarterly Report on Form 10-Q filed on August 5, 2021 and any current and periodic reports filed with the Securities and Exchange

Commission.

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

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue	\$ 2,843	\$ 488	\$ 42,536	\$ 1,750
Operating expenses:				
Research and development	22,072	21,290	46,928	43,758
General and administrative	5,937	5,255	12,878	10,720
Total operating expenses	<u>28,009</u>	<u>26,545</u>	<u>59,806</u>	<u>54,478</u>
Loss from operations	(25,166)	(26,057)	(17,270)	(52,728)
Interest income, net	48	189	75	654
Net loss	<u>\$ (25,118)</u>	<u>\$ (25,868)</u>	<u>\$ (17,195)</u>	<u>\$ (52,074)</u>
Net loss per common share, basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.69)</u>	<u>\$ (0.23)</u>	<u>\$ (1.41)</u>
Shares used to compute for net loss per common share, basic and diluted	76,749,641	37,256,247	76,368,506	37,027,405

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

(In thousands)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 64,081	\$ 170,056
Marketable securities	107,101	1,002
Prepaid expenses and other current assets	<u>5,573</u>	<u>4,332</u>
Total current assets	176,755	175,390
Property and equipment, net	21,792	22,105
Operating lease right-of-use assets	18,700	21,344
Long-term marketable securities	4,001	-
Deposits and other long-term assets	<u>2,976</u>	<u>2,728</u>
Total assets	<u>\$ 224,224</u>	<u>\$ 221,567</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,795	\$ 9,578
Accrued compensation	4,785	6,331
Accrued liabilities	736	677
Accrued research and development	2,000	1,053
Lease liabilities, current portion	6,171	5,874
Deferred revenue, current portion	<u>2,940</u>	<u>3,475</u>
Total current liabilities	21,427	26,988
Other non-current liabilities	395	395

Lease liabilities, net of current portion	16,176	19,225
Deferred revenue, net of current portion	7,401	8,220
Total liabilities	45,399	54,828
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	18	18
Additional paid-in capital	522,290	493,023
Accumulated other comprehensive gain	14	-
Accumulated deficit	(343,497)	(326,302)
Total stockholders' equity	178,825	166,739
Total liabilities and stockholders' equity	\$ 224,224	\$ 221,567

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