



# gritstone

ONCOLOGY

## Gritstone Reports Fourth Quarter and Full Year 2020 Financial Results and Business Highlights

March 11, 2021

EMERYVILLE, Calif., March 11, 2021 (GLOBE NEWSWIRE) -- Gritstone Oncology, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing next generation cancer and infectious disease immunotherapies, today reported financial results for the fourth quarter and full year ended December 31, 2020 and reviewed business highlights.

"Over this past year, we have demonstrated the significant potential of our platform technologies and have effectively transformed the profile of the company with the addition of a second therapeutic focus, expanding our pipeline programs by leveraging the distinct capabilities of Gritstone EDGE™ to identify key immune targets and our prime-boost vaccine platform to elicit a robust immune response," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone. "Our new infectious disease-focused collaborations with leading institutions augment the ongoing GRANITE and SLATE Phase 2 studies in difficult-to-treat advanced cancers, for which we expect to report data later this year. Additionally, we plan to initiate clinical trials in earlier cancer disease settings, such as the post-operative adjuvant context, where immunotherapy is typically even more effective. Finally, from an operational standpoint, we have strengthened our balance sheet with proceeds from partnerships as well as a successful PIPE financing."

### Key Accomplishments

#### Oncology Programs

- Presented preliminary efficacy, immunogenicity, and safety data up to dose level 3 (of 4) from the ongoing Phase 1 study evaluating GRANITE (an individualized neoantigen immunotherapy) in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including microsatellite stable colorectal cancer (MSS-CRC), gastroesophageal (GEA) cancer and metastatic non-small cell lung cancer (NSCLC)
  - Demonstrated consistent, strong neoantigen-specific CD8+ T cells generated in all patients tested and evidence of clinical benefit, as well as a favorable safety profile
- Presented the same data types from the Phase 1 study evaluating SLATE (a shared neoantigen immunotherapy) in combination with immune checkpoint blockade for the treatment of patients with metastatic NSCLC, pancreatic ductal adenocarcinoma and MSS-CRC, as well as in patients with other solid tumor types who have relevant mutation/human leukocyte antigen (HLA) combinations
  - Induced CD8+ T cells against multiple KRAS driver mutations, with the most pronounced response against immunodominant neoantigens such as TP53 mutation, and demonstrated a favorable safety profile
- Initiated single-arm Phase 2 expansion cohorts with GRANITE for patients with MSS-CRC who have progressed on FOLFOX/FOLFIRI therapy and a second cohort for patients with GEA who have progressed on chemotherapy
- Initiated single-arm Phase 2 expansion cohorts with SLATE v1 in NSCLC patients with relevant KRAS mutations who have progressed on prior immunotherapy, and patients with tumors where a relevant TP53 mutation exists
- Announced the selection of a bispecific antibody directed against CT83, a cancer testis antigen prevalent in common solid cancers with significant unmet need

#### Infectious Disease Programs

- Launched COVID-19 program (CORAL) to develop a second-generation vaccine against SARS-CoV-2, the virus that causes COVID-19, with potential for both prolonged protection and potency against Spike mutants, in addition to other viral antigens outside of Spike
- Received a grant from the Bill and Melinda Gates Foundation to support the preclinical evaluation of the COVID-19 vaccine
- Entered into a clinical trial agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to support the conduct of the Phase 1 CORAL clinical trial through the Infectious Diseases Clinical Research Consortium (IDCRC)
- Executed a license agreement with the La Jolla Institute for Immunology (LJI), one of the leading global organizations dedicated to studying the immune system, to access validated SARS-CoV-2 epitopes that have been identified through LJI's studies of hundreds of patients recovering from COVID-19

- Established a collaboration with Gilead Sciences (Gilead) to research and develop a vaccine-based immunotherapy as part of Gilead's efforts to find a curative treatment for human immunodeficiency virus (HIV) infection

#### Balance Sheet Strengthening

- Completed a \$125.0 million private investment in public equity (PIPE) financing in December 2020 with a small syndicate of both existing and new blue-chip life science investors
- In 2021, received \$60 million in proceeds from the Gilead collaboration, consisting of \$30.0 million in upfront cash and \$30.0 million as an equity investment at a premium to market price

#### Anticipated Upcoming Milestones

- Present additional efficacy and safety data from the Phase 1 GRANITE study, including at the higher GRANITE dose level, in the first half of 2021
- Present data from Phase 2 SLATE v1 cohorts in the first half of 2021
- Initiate new Phase 2 clinical trial cohorts for GRANITE and SLATE, including a cohort evaluating a SLATE v2 cassette optimized for KRAS neoantigens for patients with NSCLC, in the first half of 2021
- Generate Phase 1 CORAL COVID-19 vaccine data in mid-2021
- Present data from Phase 2 GRANITE cohorts in advanced MSS-CRC and gastric cancers in the second half of 2021
- Report data from SLATE v2 cassette in the first half of 2022
- Submit an Investigational New Drug (IND) application for the CT83-directed bispecific antibody in mid-2022

#### Fourth Quarter and Full Year 2020 Financial Results

For the three and twelve months ended December 31, 2020, Gritstone reported a net loss of \$27.2 million and \$105.3 million, respectively. This compares to a net loss of \$27.7 million and \$94.4 million, respectively, for the same periods in 2019.

Collaboration revenue was \$0.9 million for the three months ended December 31, 2020, and \$3.5 million for the full year 2020, compared to \$0.9 million for the three months ended December 31, 2019, and \$4.4 million for the full year 2019.

Total research and development expenses were \$22.8 million for the three months ended December 31, 2020, and \$88.6 million for the full year 2020, compared to \$23.6 million and \$82.9 million, respectively, for the same periods in 2019. The increase for the year ended December 31, 2020 was primarily due to increases in personnel related expenses and expenses related to in-house laboratory supplies and consumables and facilities expenses.

General and administrative expenses were \$5.6 million for the three months ended December 31, 2020, and \$21.4 million for the full year 2020, compared to \$5.6 million and \$19.4 million, respectively, for the same periods in 2019. The increase for the year ended December 31, 2020 was primarily due to increases in personnel related costs and expenses for professional services.

Cash, cash equivalents, marketable securities and restricted cash were \$172.1 million as of December 31, 2020, compared to \$128.8 million as of December 31, 2019. This excludes \$60 million in proceeds from the Gilead partnership, consisting of \$30 million upfront cash payment and \$30 million equity investment, which were received in the first quarter of 2021.

#### About Gritstone

Gritstone Oncology, 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. The company also has a bispecific antibody (BiSAb) program for solid tumors in lead optimization. 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, as well as 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 [gritstoneoncology.com](http://gritstoneoncology.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 Annual Report on Form 10-K filed on March 11, 2021 and any current and periodic reports filed with the Securities and Exchange Commission.

#### Contacts

Media:

Dan Budwick  
 1AB  
 (973) 271-6085  
[dan@1abmedia.com](mailto:dan@1abmedia.com)

Investors:  
 Alexandra Santos  
 Wheelhouse Life Science Advisors  
 (510) 871-6161  
[asantos@wheelhousesa.com](mailto:asantos@wheelhousesa.com)

**Gritstone Oncology, Inc.**  
**Condensed Consolidated Statements of Operations**  
 (In thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenue:				
Collaboration	\$ 917	\$ 884	\$ 3,462	\$ 4,365
Contribution	431	-	575	-
Total revenue	<u>1,348</u>	<u>884</u>	<u>4,037</u>	<u>4,365</u>
Operating expenses:				
Research and development	22,845	23,582	88,643	82,896
General and administrative	5,650	5,615	21,411	19,409
Total operating expenses	<u>28,495</u>	<u>29,197</u>	<u>110,054</u>	<u>102,305</u>
Loss from operations	(27,147)	(28,313)	(106,017)	(97,940)
Interest and other income, net	(20)	609	703	3,507
Net loss	\$ (27,167)	\$ (27,704)	\$ (105,314)	\$ (94,433)
Net loss per common share, basic and diluted	\$ (0.69)	\$ (0.77)	\$ (2.79)	\$ (2.81)
Shares used to compute for net loss per common share, basic and diluted	39,364,507	35,906,917	37,792,365	33,554,823

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

	December 31, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 170,056	\$ 57,408
Marketable securities	1,002	70,368
Prepaid expenses and other current assets	4,332	3,497
Total current assets	<u>175,390</u>	<u>131,273</u>
Property and equipment, net	22,105	26,911
Operating lease right-of-use assets	21,344	23,427
Deposits and other long-term assets	2,728	2,778
Total assets	<u>\$ 221,567</u>	<u>\$ 184,389</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 9,578	\$ 4,621
Accrued compensation	6,331	4,598
Accrued liabilities	677	1,041

Accrued research and development	1,053	1,779
Lease liabilities, current portion	5,874	2,505
Deferred revenue, current portion	3,475	4,956
Total current liabilities	26,988	19,500
Other non-current liabilities	395	-
Lease liabilities, net of current portion	19,225	20,985
Deferred revenue, net of current portion	8,220	9,560
Total liabilities	54,828	50,045
Commitments and contingencies		
Stockholders' equity:		
Common stock	18	17
Additional paid-in capital	493,023	355,291
Accumulated other comprehensive loss	-	24
Accumulated deficit	(326,302)	(220,988)
Total stockholders' equity	166,739	134,344
Total liabilities and stockholders' equity	\$ 221,567	\$ 184,389



Source: Gritstone Oncology, Inc