



# gritstone

ONCOLOGY

## Gritstone Oncology Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Highlights

March 11, 2020

EMERYVILLE, Calif., March 11, 2020 (GLOBE NEWSWIRE) -- Gritstone Oncology, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company developing the next generation of cancer immunotherapies to fight multiple cancer types, today reported financial results for the fourth quarter and full year ended December 31, 2019 and reviewed business highlights.

"Over this past year, we have achieved a number of important milestones as we drive towards proof-of-concept for our pioneering neoantigen-specific immunotherapies, SLATE and GRANITE," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "2020 is a critical year for the company, as we expect to complete dose escalation and present Phase 1 clinical data from both of these programs, as well as advance SLATE and GRANITE into later-stage development. In addition to the potential for these immunotherapies to change the treatment of advanced cancers, we believe they also hold significant promise to address unmet need in the adjuvant setting where many patients experience recurrence of disease following surgery. The scientific literature continues to emphasize the importance of neoantigen-directed CD8+ T cells in cancer immunotherapy, and our platform, developed with this in mind, is demonstrably generating unprecedented numbers of these vital cells in cancer patients."

### Key Accomplishments Over Last 12 Months

#### Pipeline Portfolio

- Reported early immunogenicity, safety and efficacy data from a Phase 1 study evaluating SLATE, our off-the-shelf targeted immunotherapy product candidate, in combination with immune checkpoint blockade for the treatment of patients with metastatic non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma and microsatellite stable colorectal cancer (MSS-CRC), as well as in patients with other solid tumor types who have relevant mutation/human leukocyte antigen (HLA) combinations
  - Comprehensive immunogenicity data focused on robust quantitation of neoantigen-specific CD8+ T cells using the standard overnight ELISpot assay in all patients
  - Efficacy data include standard radiographic imaging as well as quantitative analysis of mutant DNA in plasma over time, an emerging biomarker with potential utility as both a patient selection tool and surrogate efficacy endpoint
- Reported the same data types from a Phase 1 study evaluating GRANITE, our individualized product candidate, in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including MSS-CRC, gastroesophageal cancer, metastatic NSCLC, and bladder cancer
- Extended our clinical trial collaboration and supply agreement with Bristol-Myers Squibb to use their immune checkpoint inhibitors nivolumab and ipilimumab in the Phase 1 study of SLATE
- Presented a poster at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting describing multiple novel shared tumor-specific neoantigens (TSNA) derived from driver mutations (such as KRAS G12C) that were identified and validated by combining the Gritstone EDGE™ machine learning platform with tumor HLA peptide sequencing. These neoantigens are contained within the first SLATE product candidate.
- Delivered an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting demonstrating that EDGE improved the positive predictive value for human leukocyte antigen class II (HLA-DR) peptide presentation over standard methods by ~20-fold
- Improved the performance of the EDGE platform to show a positive predictive value for HLA class I peptide presentation of ~75%, which is an estimated 10-fold improvement over leading public tools
- Presented a poster at AACR demonstrating Gritstone's capabilities to efficiently identify neoantigen-reactive T cells and T cell receptors, which have potential applications in cell therapy

#### Business Operations

- Completed a successful public follow-on offering of common stock, raising approximately \$74.8 million in gross proceeds
- Internalized additional manufacturing operations for the production of SLATE and GRANITE immunotherapies at Gritstone's ~43,000 sq. ft. fully integrated GMP biomanufacturing facility in Pleasanton, California, enabling:

- Control over manufacturing slots and timelines
  - Innovative process development to reduce turnaround time and cost of goods
  - Careful management of relevant intellectual property, including patents, trade secrets and know-how
- Appointed Vijay Yabannavar, Ph.D., a biopharma leader with over 30 years of experience, as executive vice president of manufacturing and technical operations
- Appointed a new board member, Elaine V. Jones, Ph.D., who has two decades of life science investing experience, has served on over 20 life science company boards, and has direct experience within biopharma research and business development
- Appointed Mike Forcht, Ed.D., M.B.A., with more than 20 years of global management experience, as senior vice president of people and corporate services
- Augmented the Scientific Advisory Board with Eugene Zhukovsky, Ph.D., an expert in the development of bispecific biotherapeutics

#### **Anticipated Upcoming Milestones**

- Present additional efficacy and safety data from the Phase 1 studies of SLATE and GRANITE at an upcoming scientific congress by mid-2020
- For SLATE, initiate Phase 2 expansion cohorts in patients with third-line MSS-CRC, refractory/resistant NSCLC and pancreatic cancer in the second half of 2020
- For GRANITE, initiate Phase 2 expansion cohorts in patients with third-line MSS-CRC and second-line gastro-esophageal cancers in the second half of 2020
- Nominate a lead bispecific antibody development candidate directed towards a novel solid tumor-specific HLA-peptide complex in the second half of 2020
- Initiate a Phase 2 adjuvant study in high-risk localized tumors, such as NSCLC, pancreatic cancer and MSS-CRC, with SLATE in the first half of 2021
- Initiate a Phase 2 adjuvant study in high-risk localized tumors, such as NSCLC and gastro-esophageal adenocarcinoma, with GRANITE in the first half of 2021

#### **Fourth Quarter and Full Year 2019 Financial Results**

For the three and twelve months ended December 31, 2019, Gritstone reported a net loss of \$27.7 million and \$94.4 million, respectively. This compares to a net loss of \$17.3 million and \$64.8 million, respectively, for the same periods in 2018.

Collaboration revenue was \$0.9 million for the three months ended December 31, 2019, and \$4.4 million for the full year 2019, compared to \$1.1 million for the three months ended December 31, 2018, and \$1.2 million for the full year 2018. The year-over-year increase was due to a full year of revenue recognized under the Research Collaboration and License Agreement with bluebird during 2019.

Total research and development expenses were \$23.6 million for the three months ended December 31, 2019, and \$82.9 million for the full year 2019, compared to \$15.3 million and \$55.0 million, respectively, for the same periods in 2018. The increase was primarily attributable to an increase in personnel-related expenses driven by increased headcount, as well as an increase in outside services and consultants, in-house laboratory supplies and consumables, and facilities-related expenses.

General and administrative expenses were \$5.6 million for the three months ended December 31, 2019, and \$19.4 million for the full year 2019, compared to \$3.9 million and \$11.8 million, respectively, for the same periods in 2018. The increase was primarily attributable to an increase in personnel-related expenses driven by an increase in headcount and an increase in legal and other outside professional services required to support the company's ongoing operations as a public company.

Cash, cash equivalents, and marketable securities were \$128.8 million as of December 31, 2019, compared to \$153.1 million as of December 31, 2018.

#### **About Gritstone Oncology**

Gritstone Oncology (Nasdaq: GRTS), a clinical-stage biotechnology company, is developing the next generation of cancer immunotherapies to fight multiple cancer types. Gritstone develops its products by leveraging two key pillars—first, a proprietary machine learning-based platform, Gritstone EDGE, which is designed to predict, from a routine tumor biopsy, the tumor-specific neoantigens (TSNA) that are presented on a patient's tumor cells; and second, the ability to develop and manufacture potent immunotherapies utilizing patients' TSNA to potentially drive the patient's immune system to specifically attack and destroy tumors. The company's "off the shelf" shared neoantigen-based immunotherapy, SLATE, and its individualized neoantigen-based immunotherapy, GRANITE, are being evaluated in Phase 1 clinical studies. Novel tumor-specific antigens can also provide targets for bispecific antibody (BiSAb) therapeutics for solid tumors, and Gritstone's BiSAb program is currently in lead optimization. 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, including the timing thereof. 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, 2020 and any current and periodic reports filed with the Securities and Exchange Commission.

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## Gritstone Oncology, Inc.

### Condensed Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Collaboration revenue	\$ 884	\$ 1,091	\$ 4,365	\$ 1,187
Operating expenses:				
Research and development	\$ 23,582	15,252	82,896	54,965
General and administrative	\$ 5,615	3,866	19,409	11,806
Total operating expenses	29,197	19,118	102,305	66,771
Loss from operations	(28,313)	(18,027)	(97,940)	(65,584)
Interest and other income, net	\$ 609	690	3,507	809
Net loss	\$ (27,704)	\$ (17,337)	\$ (94,433)	\$ (64,775)
Net loss per common share, basic and diluted	\$ (0.77)	\$ (0.61)	\$ (2.81)	\$ (7.26)
Shares used to compute for net loss per common share, basic and diluted	35,906,917	28,443,460	33,554,823	8,919,281

## Gritstone Oncology, Inc.

### Condensed Balance Sheets

(Unaudited)

(In thousands)

	December 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 57,408	\$ 52,183
Marketable securities	70,368	100,927
Prepaid expenses and other current assets	3,497	4,526
Total current assets	131,273	157,636
Property and equipment, net	26,911	29,494
Operating lease right-of-use assets	23,427	-
Deposits and other long-term assets	2,778	2,428
Total assets	\$ 184,389	\$ 189,558

### Liabilities and stockholders' equity

Current liabilities:		
Accounts payable	\$ 4,621	\$ 4,825
Accrued compensation	4,598	3,951
Accrued liabilities	1,041	740
Accrued research and development	1,779	252
Lease liabilities, current portion	2,505	-
Deferred revenue, current portion	4,956	5,340
Total current liabilities	19,500	15,108
Deferred rent, net of current portion	-	1,353
Other non-current liabilities	-	12
Lease financing obligation, net of current portion	-	10,490
Lease liabilities, net of current portion	20,985	-
Deferred revenue, net of current portion	9,560	13,473
Total liabilities	50,045	40,436
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	-	-
Common stock	17	16
Additional paid-in capital	355,291	275,593
Accumulated other comprehensive loss	24	(85)
Accumulated deficit	(220,988)	(126,402)
Total stockholders' equity	134,344	149,122
Total liabilities and stockholders' equity	\$ 184,389	\$ 189,558



Source: Gritstone Oncology, Inc