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Gritstone Oncology Reports First Quarter Financial Results and Recent Highlights

May 7, 2020

EMERYVILLE, Calif., May 07, 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 first quarter ended March 31, 2020 and reviewed business highlights.

"We began this year by presenting the first-ever clinical data of its kind, demonstrating that an immunotherapy can prime and boost a strong CD8+ T cell response against tumor-specific neoantigens," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "The early clinical results from our Phase 1 studies of GRANITE and SLATE are another critical step towards our ultimate goal of broadening the clinical benefits of immunotherapy for patients with solid tumors. We will host a webcasted investor event mid-year to present updated data from these trials. Since the company's inception in 2015, we have built a best-in-class neoantigen prediction capability (Gritstone EDGE™); we have designed a potent novel vaccine vector system to prime and boost strong CD8+ T cell responses in humans to encoded neoantigens; we have established a state-of-the-art biomanufacturing facility; and we have now shown in early Phase 1 studies in patients with end-stage disease that this biology can be successfully and safely deployed. We are very close to initiating phase 2 trials in patients with less advanced disease where we expect neoantigen-directed immunotherapy to exhibit greatest clinical benefit. The adjuvant opportunities are particularly exciting given the power of new technologies that measure circulating tumor DNA to identify patients at very high risk of disease recurrence after attempted curative surgical therapy. We have several Phase 2 study initiations expected to occur over the next 12 months, and while we currently anticipate nominal impact from COVID-19 on our trial timelines, we are monitoring this situation closely. As an organization, we have strengthened our operations with the expansion of our in-house manufacturing capabilities and the appointment of additional experienced executives to our team. Finally, we expect that our cash position will support our important development work through key program milestones into the third quarter of 2021."

Recent Accomplishments

- Reported early immunogenicity, safety and efficacy data from a Phase 1 study evaluating GRANITE, an individualized product candidate, in combination with immune checkpoint blockade for the treatment of patients with advanced solid tumors, including microsatellite stable colorectal cancer (MSS-CRC), gastroesophageal cancer, metastatic non-small cell lung cancer (NSCLC), and bladder cancer
- Reported the same data types from a Phase 1 study evaluating SLATE, an off-the-shelf targeted immunotherapy product candidate, 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
- Appointed Rahsaan W. Thompson, J.D., veteran legal executive with over 20 years of corporate counsel experience, as executive vice president and general counsel
- Appointed Elaine V. Jones, Ph.D., an existing board member, to the position of chairman of the board of directors
- 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

Anticipated Upcoming Milestones

- Present additional efficacy and safety data from the Phase 1 studies of SLATE and GRANITE in a company-hosted webcast event in mid-2020
- Initiate Phase 2 expansion cohorts in the second half of 2020
- Initiate Phase 2 adjuvant study/studies in early 2021
- Nominate a lead bispecific antibody development candidate directed towards a novel solid tumor-specific HLA-peptide complex in the second half of 2020

First Quarter 2020 Financial Results

For the three months ended March 31, 2020, Gritstone reported a net loss of \$26.2 million, compared to a net loss of \$18.0 million for the three months ended March 31, 2019.

Collaboration revenue was \$1.3 million for the three months ended March 31, 2020, compared to \$1.3 million for the three months ended March 31, 2019. Collaboration revenue was due to the Research Collaboration and License Agreement with bluebird bio Inc. and another small collaboration

agreement.

Total research and development expenses were \$22.5 million for the three months ended March 31, 2020, compared to \$15.9 million for the three months ended March 31, 2019. 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 \$5.5 million for the three months ended March 31, 2020, compared to \$4.4 million for the three months ended March 31, 2019. 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, marketable securities and restricted cash were \$109.9 million as of March 31, 2020, compared to \$128.8 million as of December 31, 2019.

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.

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 Quarterly Report on Form 10-Q filed on May 7, 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	
	March 31,	
	2020	2019
Collaboration revenue	\$ 1,262	\$ 1,347
Operating expenses:		
Research and development	\$ 22,468	15,899
General and administrative	\$ 5,465	4,377
Total operating expenses	27,933	20,276
Loss from operations	(26,671)	(18,929)
Interest and other income, net	\$ 465	920

Net loss	\$ (26,206)	\$ (18,009)
Net loss per common share, basic and diluted	\$ (0.71)	\$ (0.62)
Shares used to compute for net loss per common share, basic and diluted	36,798,562		28,938,891	

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

	March 31, 2020		December 31, 2019	
Assets				
Current assets:				
Cash and cash equivalents	\$ 54,860		\$ 57,408	
Marketable securities	54,020		70,368	
Prepaid expenses and other current assets	3,466		3,497	
Total current assets	112,346		131,273	
Property and equipment, net	25,847		26,911	
Operating lease right-of-use assets	22,130		23,427	
Deposits and other long-term assets	2,695		2,778	
Total assets	\$ 163,018		\$ 184,389	
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$ 5,008		\$ 4,621	
Accrued compensation	2,775		4,598	
Accrued liabilities	414		1,041	
Accrued research and development	2,311		1,779	
Lease liabilities, current portion	3,421		2,505	
Deferred revenue, current portion	4,511		4,956	
Total current liabilities	18,440		19,500	
Lease liabilities, net of current portion	20,101		20,985	
Deferred revenue, net of current portion	9,088		9,560	
Total liabilities	47,629		50,045	
Commitments and contingencies				
Stockholders' equity:				
Convertible preferred stock	-		-	
Common stock	17		17	
Additional paid-in capital	362,586		355,291	
Accumulated other comprehensive loss	(20)	24	
Accumulated deficit	(247,194)	(220,988)
Total stockholders' equity	115,389		134,344	
Total liabilities and stockholders' equity	\$ 163,018		\$ 184,389	



Source: Gritstone Oncology, Inc