



Gritstone bio Reports Second Quarter 2024 Financial Results and Provides Corporate Updates

August 13, 2024

-- Preliminary randomized Phase 2 data suggest GRANITE (personalized neoantigen vaccine) could drive meaningful clinical benefit in front-line metastatic microsatellite-stable colorectal cancer (MSS-CRC); mature progression-free survival (PFS) data expected in the third quarter of 2024 --

-- Recent KOL event and patient advocacy engagements underscore the unmet need for new treatment options in metastatic colorectal cancer --

-- Presentations at AACR 2024 and ESCMID Global 2024 demonstrate the broad potential of Gritstone's oncology and infectious disease vaccines --

-- Cash, cash equivalents, marketable securities and restricted cash of \$61.7 million as of June 30, 2024 --

EMERYVILLE, Calif., Aug. 13, 2024 (GLOBE NEWSWIRE) -- Gritstone bio, Inc. (Nasdaq: GRTS), a clinical-stage biotechnology company working to develop the world's most potent vaccines, today reported financial results for the second quarter ended June 30, 2024 and provided recent corporate and clinical updates.

"This is an exciting time for Gritstone, as we are on the cusp of unlocking important data about our promising new therapeutic modality in front-line metastatic microsatellite-stable colorectal cancer (MSS-CRC)," said Andrew Allen, MD, PhD, Co-founder, President & CEO of Gritstone bio. "Up to 95% of patients with metastatic CRC, the second most common cause of cancer death, are MSS. Delivering a new treatment option to these patients, who do not benefit from today's immunotherapies, would be transformative. The emerging progression-free survival (PFS) benefit we reported in April is highly encouraging, especially in this tough to treat patient population. We have waited for these clinical data to mature and look forward to sharing the updated dataset next month. If we continue to see evidence of a clinical benefit with GRANITE, as measured by PFS, we believe new hope can be brought to patients who have not been helped by immune checkpoint blockade."

Dr. Allen added, "Along with advancing GRANITE in CRC, our team continues to innovate across our programs, reinforcing the potential of our underlying technologies. Our recent AACR presentation highlights the unique power of EDGE™, our proprietary neoantigen identification platform that underpins all our programs. Our recent presentation at ESCMID showcases the ability of our self-amplifying mRNA vector (samRNA) to induce long-lasting immune responses. Gritstone remains uniquely positioned to deliver on the promise of next-generation vaccine technologies to prevent, treat and eradicate disease."

Corporate Updates

- In April 2024, Gritstone completed an underwritten public offering resulting in gross proceeds of \$32.5 million.
- In April 2024, Gritstone appointed Stephen Webster to its Board of Directors. A veteran finance executive with over 30 years in the biotechnology industry, Mr. Webster has held several key roles and been involved in multiple strategic transactions. Mr. Webster was the Chief Financial Officer of Spark Therapeutics from July 2014 until its acquisition by Roche for \$4.3 billion in December 2019.
- In July 2024, Gritstone bio engaged the Colorectal Cancer Alliance and the Paltown Development Foundation 501(c)(3), the fiduciary for Colontown.org, as part of its effort to educate and empower patients living with colorectal cancer and their caregivers.
- In August 2024, Gritstone bio held a virtual KOL event to discuss the unmet need and potential role of GRANITE in metastatic microsatellite-stable colorectal cancer (MSS-CRC). The event featured J. Randolph Hecht, MD, Professor of Clinical Medicine and Director of the UCLA GI Oncology Program, and Howard Brown, CRC Survivor, Patient and Advocate. Details [here](#).

Clinical Program Updates

Tumor-Specific Neoantigen Oncology Programs (GRANITE and SLATE)

GRANITE – Personalized neoantigen vaccine program

SLATE – "Off-the-shelf" neoantigen vaccine program

- **Preliminary results (reported April 1, 2024) from the ongoing randomized Phase 2 study suggest GRANITE could drive meaningful clinical benefit in front-line metastatic microsatellite-stable colorectal cancer (MSS-CRC). Gritstone expects to report mature progression-free survival (PFS) data in 3Q 2024.**
 - Preliminary data, while immature, showed a trend of extended PFS in GRANITE-treated vs. control patients.
 - Hazard ratio of 0.82 (18% relative risk reduction of progression or death with GRANITE vs. control) in the overall population, where clinical data are less mature ([95% CI, 0.34-1.67]; 62% censored)
 - Hazard ratio of 0.52 (48% relative risk reduction of progression or death with GRANITE vs. control) in a fast-progressor, i.e. 'high-risk' group ¹, where clinical data are more mature ([95% CI, 0.15-1.38]; 44% censored). Too few events in the slow-progressor group at this early look to draw any efficacy conclusions.

¹Fast-progressor subgroup defined as baseline ctDNA above the median value (2%) for the control group

(ctDNA quantified as mean variant allele frequency [VAF] at time of study randomization).

- o Long-term circulating tumor DNA (ctDNA) data aligned with PFS trend and favored GRANITE vs. control patients
- **EDGE™ predicts HLA Class I presentation with >80% accuracy**In April 2024, Gritstone presented an update on the predictive performance of both HLA Class I and HLA Class II presentation at the 2024 American Association for Cancer Research (AACR) Annual Meeting in San Diego, CA. [The findings](#) further Gritstone's belief that EDGE is leading the field in neoantigen prediction.
- **The clinical trial collaboration with the National Cancer Institute (NCI) to evaluate an autologous mutant KRAS-directed TCR-T cell therapy in combination with SLATE-KRAS, Gritstone's KRAS-directed "off-the-shelf" vaccine candidate, is ongoing.** The study is led by Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI's Center for Cancer Research and builds into the growing interest in combining tumor-antigen specific cell therapy with matched vaccines.

Infectious Disease Programs

CORAL – Next-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's samRNA platform and novel approach in infectious diseases

- **Efforts to initiate a head-to-head Phase 2b study of Gritstone's next-generation COVID-19 vaccine (the CORAL Phase 2b study) per the Biomedical Advanced Research and Development Authority (BARDA)² contract continue.** Gritstone will provide further updates as it is able.
- **Follow up data from the Phase 1 CORAL study highlight the durability and potential broad utility of Gritstone's samRNA COVID-19 vaccine.** In April 2024, Gritstone presented 12-month follow up data from the Phase 1 CORAL-CEPI at ESCMID 2024. [The results](#) reinforced previous findings showing induction of broad and durable immune responses through 12 months.

HIV – Collaboration with Gilead to research and develop vaccine-based HIV immunotherapy treatment

- **The collaboration with Gilead to research and develop a vaccine-based HIV immunotherapy treatment continues under Gilead's direction.**

Second Quarter 2024 Financial Results

- **Cash, cash equivalents, marketable securities and restricted cash** were \$61.7 million as of June 30, 2024, compared to \$52.8 million as of March 31, 2024.
- **Research and development expenses** were \$20.8 million for the three months ended June 30, 2024, compared to \$31.0 million for the three months ended June 30, 2023. The decrease of \$10.2 million for the three months ended June 30, 2024, compared to the three months ended June 30, 2023 was primarily due to decreases of \$3.2 million in personnel-related expenses, \$3.2 million in laboratory supplies, \$2.6 million in outside services, consisting primarily of clinical trial and other chemistry, manufacturing and controls related expenses and \$1.2 million in facilities related costs.
- **General and administrative expenses** were \$7.7 million for the three months ended June 30, 2024, compared to \$6.7 million for the three months ended June 30, 2023. The increase of \$1.0 million was primarily attributable to increases of \$0.9 million in personnel-related expenses, including a \$0.5 million increase of non-cash stock-based compensation, and \$0.1 million in facilities related costs.
- **Grant revenues** were \$0.9 million for the three months ended June 30, 2024. During the three months ended June 30, 2024, we recorded \$0.9 million in grant revenue from CEPI.

² This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00062.

About Gritstone bio

Gritstone bio, Inc. (Nasdaq: GRTS) is a clinical-stage biotechnology company that aims to develop the world's most potent vaccines. We leverage our innovative vectors and payloads to train multiple arms of the immune system to attack critical disease targets. Independently and with our collaborators, we are advancing a portfolio of product candidates to treat and prevent viral diseases and solid tumors in pursuit of improving patient outcomes and eliminating disease. www.gritstonebio.com

Gritstone Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to our clinical and regulatory development

plans for our product candidates; our expectations regarding the data to be derived in our ongoing and planned clinical trials; the timing of commencement of our future nonclinical studies, clinical trials and research and development programs; our ability to discover, develop and advance product candidates into, and successfully complete, clinical trials; and our plans and strategy regarding maintaining existing and entering into new collaborations and/or partnerships. 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' clinical 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 5, 2024 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

This press release concerns drugs that are under clinical investigation, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 50,900	\$ 62,986
Marketable securities	4,812	16,288
Restricted cash	1,274	2,299
Prepaid expenses and other current assets	3,724	5,862
Total current assets	60,710	87,435
Long-term restricted cash	4,695	5,290
Property and equipment, net	12,527	17,281
Lease right-of-use assets	64,001	66,839
Deposits and other long-term assets	609	924
Total assets	\$ 142,542	\$ 177,769
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,132	\$ 3,819
Accrued compensation	5,272	9,357
Accrued liabilities	856	1,213
Accrued research and development expenses	3,002	3,696
Lease liabilities, current portion	7,159	6,904
Deferred revenue, current portion	698	2,350
Warrant liability	2,782	—
Total current liabilities	23,901	27,339
Other liabilities, noncurrent	1,117	709
Lease liabilities, net of current portion	54,829	57,727
Debt, noncurrent	40,506	40,144
Total liabilities	120,353	125,919
Stockholders' equity:		
Preferred stock	—	—
Common stock	24	22
Additional paid-in capital	745,510	711,386
Accumulated other comprehensive (loss) gain	(3)	3
Accumulated deficit	(723,342)	(659,561)

Total stockholders' equity		22,189		51,850
Total liabilities and stockholders' equity	\$	142,542	\$	177,769

Gritstone bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Collaboration and license revenues	\$ 57	\$ 400	\$ 106	\$ 941
Grant revenues	864	1,555	2,557	3,456
Total revenues	<u>921</u>	<u>1,955</u>	<u>2,663</u>	<u>4,397</u>
Operating expenses:				
Research and development	20,811	30,967	53,852	61,481
General and administrative	7,698	6,716	16,200	13,461
Total operating expenses	<u>28,509</u>	<u>37,683</u>	<u>70,052</u>	<u>74,942</u>
Loss from operations	(27,588)	(35,728)	(67,389)	(70,545)
Interest income	691	1,479	1,403	3,157
Interest expense	(1,304)	(985)	(2,600)	(1,828)
Other income (expense)	4,805	(22)	4,805	(22)
Net loss	<u>(23,396)</u>	<u>(35,256)</u>	<u>(63,782)</u>	<u>(69,238)</u>
Other comprehensive loss:				
Unrealized loss on marketable securities	(2)	(73)	(6)	(45)
Comprehensive loss	<u>\$ (23,398)</u>	<u>\$ (35,329)</u>	<u>\$ (63,787)</u>	<u>\$ (69,283)</u>
Net loss per share, basic and diluted	\$ (0.16)	\$ (0.31)	\$ (0.49)	\$ (0.60)
Weighted-average number of shares used in computing net loss per share, basic and diluted	143,296,662	114,929,523	130,843,943	114,676,261

