# Gritstone bio Reports First Quarter 2023 Financial Results and Provides Corporate Updates

May 11, 2023

*-- Robust enrollment in Phase 2 portion of randomized Phase 2/3 study of GRANITE (personalized vaccine in first-line metastatic microsatellite-stable colorectal cancer [MSS-CRC]) to date; 71 of 80 patients (initial target) enrolled as of May 10, 2023 --*

*-- Gritstone prioritizing GRANITE; expanding Phase 2 from 80 to 100 patients, enrollment completion expected in 3Q2023, preliminary data on approximately 50 patients expected in 1Q2024 --*

*-- Cash, cash equivalents, marketable securities, and restricted cash of $153.2 million as of March 31, 2023 --*

*-- Gritstone to host conference call today at 4:30pm ET --*

EMERYVILLE, Calif., May 11, 2023 (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 first quarter ended March 31, 2023 and provided recent corporate and clinical updates.

"Strategically prioritizing GRANITE underscores our conviction in the program and focuses our near-term resources on the immense opportunity that lies directly ahead of us: potentially being the first to demonstrate efficacy of a neoantigen-based personalized cancer vaccine in a randomized, controlled trial for MSS-CRC," said Andrew Allen, M.D., Ph.D., Co-founder, President, and Chief Executive Officer of Gritstone bio. "GRANITE is a potentially transformative therapy that has already shown significant promise in our published Phase 1/2 study in patients with metastatic MSS-CRC, who had received two prior lines of chemotherapy. The high demand seen to date for our ongoing Phase 2 is a testament to its potential. Expanding the study from 80 to 100 patients not only increases the statistical power of the study but also generates more time-to-event data to help inform the Phase 3. We are thrilled to have the momentum and capital to expand this study and take this important step forward for patients with newly diagnosed metastatic CRC, as well as those being treated for CRC in the adjuvant setting and other cold tumors. We look forward to sharing preliminary Phase 2 efficacy data from approximately half of the 100 total patients in the first quarter of 2024."

Dr. Allen continued, "Along with the significant progress in GRANITE, the data flowing from our CORAL program is highly encouraging and provides early signals of the potential advantages of self-amplifying mRNA (samRNA) over first-generation mRNA against infectious disease. We recently observed durable neutralizing antibody titers at 6 months following samRNA vaccination in over 100 vaccine-naïve subjects treated within our CORAL-CEPI trial, where interim results were presented at ECCMID 2023. Self-amplifying mRNA has several distinct characteristics including prolonged and elevated antigen expression that suggest it could play a key role in the induction of long-term, variant-proof immune protection. We look forward to continuing to work with our collaborators to demonstrate the full potential of our samRNA platform against SARS-CoV-2 and other important viruses."

**Corporate Updates**

***GRANITE (individualized neoantigen vaccine against cold tumors):*** Gritstone is focusing its resources to expand the ongoing Phase 2 portion of the Phase 2/3 study, which is evaluating GRANITE as a maintenance therapy in first-line metastatic microsatellite-stable colorectal cancer (MSS-CRC). As of May 10, 2023, the company had randomized 71 of the initially planned 80 total patients. The company plans to expand the study to randomize 100 patients in total. Enrollment of all 100 patients is expected to complete in third quarter of 2023 and preliminary data on approximately 50 of the 100 patients from the Phase 2 portion of the study (circulating tumor DNA [ctDNA] and progression-free survival data [evaluated by both RECIST and iRECIST criteria] on patients completing at least 4 months of treatment) is expected in the first quarter of 2024.

***SLATE ("off-the-shelf" neoantigen vaccine program):*** Given the strategic decision to focus on GRANITE, the company is deferring the initiation of a randomized Phase 2 clinical trial with SLATE until 2024. Previously, a KRAS-dedicated version of SLATE demonstrated strong T cell responses and an observed survival advantage among molecular responders in Phase 1/2 studies of patients with MSS-CRC and non-small cell lung cancer (NSCLC, press release announcing ESMO 2022 data available here). The company believes success in GRANITE has the potential to further validate the company's neoantigen-based approach, which SLATE and GRANITE share, and that SLATE is ready for application across solid tumor indications and shared tumor neoantigen classes.

***Infectious Disease:*** The company will continue its ongoing clinical and preclinical infectious disease efforts as planned, with the vast majority of these efforts being funded via external collaborators. The Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI) and the National Institute of Allergy and Infectious Diseases (NIAID) support the company's CORAL program. Gilead Sciences, Inc. (Gilead) is conducting a Phase 1 study as part of a collaboration with Gritstone to research and develop a therapeutic vaccine against HIV.

**Clinical Program Updates**
**Tumor-Specific Neoantigen Oncology Programs (GRANITE and SLATE)**

- **In April 2023, Gritstone delivered multiple presentations detailing advances in neoantigen prediction capabilities and cancer vaccine programs at the 2023 American Association for Cancer Research (AACR 2023).**
  - GRANITE (individualized neoantigen program) presentation: Longitudinal analysis of participants in the GRANITE Phase 1/2 supports vaccine-elicited priming and boosting of antigen-specific T cell populations associated with conversion of "cold" to "hot" tumors and molecular responses.
  - EDGE™ (Epitope Discovery for Genomes Platform) poster: Advances in EDGE™ models (Gritstone's AI-driven

neoantigen prediction platform) enable potential best-in-class prediction of class II HLA-presented neoantigens that could drive CD4+ T cell responses.
    - SLATE ("off-the-shelf" neoantigen vaccine program) poster : Description of a novel KRAS G12C class II epitope with evidence of clinical benefit associated with vaccine-elicited T cell response.
- **In February 2023, Gritstone announced it had entered into a clinical trial agreement with the National Cancer Institute** to evaluate an autologous T cell therapy expressing a T cell receptor targeting mutated KRAS in combination with Gritstone's KRAS-directed vaccine candidate, SLATE-KRAS, in a Phase 1 study led by Steven A. Rosenberg, M.D., Ph.D.

**Infectious Disease Programs**

*CORAL – Second-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's infectious disease approach and the potential application of samRNA in infectious diseases.*

- **In all studies to date, results have shown Gritstone's samRNA vaccine candidates to be well-tolerated and capable of driving strong, durable and broad immunogenicity across several subject populations and settings.**
- **In April 2023, Gritstone presented new data from two ongoing Phase 1 studies demonstrating persistence of high neutralizing antibodies for at least 6 months following samRNA vaccine across multiple settings and subject populations.** Both datasets were presented at the 33rd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2023).
    - CORAL-CEPI poster: Results from Part A of the CORAL-CEPI study (total study n = 342), primary series samRNA vaccination showed to elicit strong neutralizing antibody (nAb) responses that persist for at least 6 months, including variant cross-reactive nAb, in previously unvaccinated ("vaccine-naïve") South African subjects. Enrollment in CORAL-CEPI completed in February 2023.
    - CORAL-BOOST poster: Results from cohorts 3 and 4 of the CORAL-BOOST study show the samRNA elicited robust nAbs, and that these nAbs persisted for at least 6 months regardless of primary series (adenovirus or mRNA). These results are generally consistent with 6-month neutralizing antibody results from cohorts 1 and 2 of the study, which evaluated samRNA as a boost following Vaxzevria (adenovirus) only (August 2022).

- **Enrollment in the CORAL-NIH trial completed in 2022.** This study is sponsored and executed by NIAID.

*HIV – Collaboration with Gilead under Gilead's HIV Cure Program to research and develop vaccine-based HIV immunotherapy treatment.*

- **The collaboration with Gilead to research and develop a vaccine-based HIV immunotherapy treatment remains active and ongoing.**
- **In February 2023, results from a preclinical study conducted in collaboration with Gilead were presented at Conference on Retroviruses and Opportunistic Infections (CROI) 2023.** The first data disclosed from the Gritstone-Gilead HIV Cure collaboration, results showed that simian immunodeficiency virus (SIV) Chimpanzee Adenovirus (ChAd) and self-amplifying mRNA (samRNA) vaccines induced a strong and broad CD8+ T cell immune response, which was significantly enhanced in combination with immune modulators.

**First Quarter 2023 Financial Results**

- **Cash, cash equivalents, marketable securities and restricted cash** were $153.2 million as of March 31, 2023, compared to $185.2 million as of December 31, 2022.
- **Research and development expenses** were $30.5 million for the three months ended March 31, 2023 compared to $28.2 million for the three months ended March 31, 2022. The increase of $2.3 million was primarily due to increases of $1.5 million in personnel-related expenses, $0.3 million in outside services, $0.7 million in facilities related costs, and $0.8 million in laboratory supplies, offset by a decrease of $1.0 million in milestone and license payments.
- **General and administrative expenses** were $6.7 million for the three months ended March 31, 2023 compared to $8.0 million for the three months ended March 31, 2022. The decrease of $1.3 million was primarily attributable to decreases of $1.1 million in outside services and $0.2 million in facilities-related costs.
- **Collaboration, license, and grant revenues** were $2.4 million for the three months ended March 31, 2023 compared to $7.2 million for the three months ended March 31, 2022. During the three months ended March 31, 2023, we recorded $0.1 million in collaboration revenue related to our collaboration with Gilead, $0.4 million in collaboration revenue related to our collaboration with 2seventy bio, Inc., $1.5 million in grant revenue from CEPI, and $0.4 million in grant revenue from the Gates Foundation. During the three months ended March 31, 2022, we recognized $4.0 million in collaboration revenue related to our collaboration with 2seventy bio, $0.7 million in collaboration revenue related to our collaboration with Gilead, $2.2 million in grant revenue from CEPI, and $0.2 million in grant revenue from the Gates Foundation.

**Webcast Details**

**A webcast to discuss first quarter 2023 results will be held at 4:30pm ET today (May 11):**
Conference call: 1-888-999-6281
Conference ID: 1754341
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1612896&tp_key=c6c637ac24

An archived replay will be accessible at https://ir.gritstonebio.com/investors/events for 30 days following the event.

**About Gritstone bio**
Gritstone is working to create 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 and have programs in viral diseases and solid tumors. Independently and with our partners, we are advancing a portfolio of product candidates with the aim 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 9, 2023 and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 47,128 | $ 55,498 |
| Marketable securities | 98,680 | 116,389 |
| Restricted cash | 2,077 | 3,977 |
| Prepaid expenses and other current assets | 6,880 | 7,014 |
| Total current assets | 154,765 | 182,878 |
| Long-term restricted cash | 5,290 | 5,290 |
| Property and equipment, net | 20,365 | 21,335 |
| Lease right-of-use assets | 15,615 | 17,481 |
| Deposits and other long-term assets | 13,917 | 9,739 |
| Long-term marketable securities | — | 4,031 |
| Total assets | $ 209,952 | $ 240,754 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,975 | $ 8,694 |
| Accrued compensation | 4,697 | 8,215 |
| Accrued liabilities | 3,123 | 4,124 |
| Accrued research and development expenses | 3,448 | 3,343 |
| Lease liabilities, current portion | 4,628 | 5,294 |
| Deferred revenue, current portion | 2,801 | 5,131 |
| Total current liabilities | 24,672 | 34,801 |
| Other liabilities, noncurrent | 251 | 150 |
| Lease liabilities, net of current portion | 14,575 | 15,673 |
| Debt, noncurrent | 29,576 | 19,349 |
| Total liabilities | 69,074 | 69,973 |

| | | |
|---|---|---|
| Stockholders' equity: | | |
| Preferred stock | — | — |
| Common stock | 22 | 22 |
| Additional paid-in capital | 695,961 | 691,910 |
| Accumulated other comprehensive loss | (52) | (80) |
| Accumulated deficit | (555,053) | (521,071) |
| Total stockholders' equity | 140,878 | 170,781 |
| Total liabilities and stockholders' equity | $ 209,952 | $ 240,754 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Revenues: | | |
| Collaboration and license revenues | $ 542 | $ 4,745 |
| Grant revenues | 1,901 | 2,446 |
| Total revenues | 2,443 | 7,191 |
| Operating expenses: | | |
| Research and development | 30,514 | 28,199 |
| General and administrative | 6,745 | 7,955 |
| Total operating expenses | 37,259 | 36,154 |
| Loss from operations | (34,816) | (28,963) |
| Interest income | 1,678 | 71 |
| Interest expense | (844) | (24) |
| Net loss | (33,982) | (28,916) |
| Other comprehensive loss: | | |
| Unrealized gain (loss) on marketable securities | 28 | (318) |
| Comprehensive loss | $ (33,954) | $ (29,234) |
| Net loss per share, basic and diluted | $ (0.30) | $ (0.34) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 114,423,000 | 86,277,599 |