

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

May 11, 2023
Date of Report (date of earliest event reported)

Prime Medicine, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-41536
(Commission File Number)

84-3097762
(I.R.S. Employer Identification No.)

21 Erie Street
Cambridge, MA 02139
(Address of principal executive offices and zip code)
(617) 564-0013
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, par value \$.00001 per share	PRME	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§250.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2023, Prime Medicine, Inc. (the “Company”) issued a press release announcing its financial results and business highlights for the quarter ended March 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 - Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated May 11, 2023, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Prime Medicine Reports First Quarter 2023 Financial Results and Provides Business Updates

-- New data further demonstrating ability of Prime Editing to correct causative mutation of CGD and highlighting potential of PASSIGE platform to multiplex edit CAR-T cells to be presented at ASGCT Annual Meeting --

-- Expanded Board of Directors with appointment of Jeff Marrazzo, former CEO of Spark Therapeutics --

-- Further extended intellectual property portfolio; U.S. PTO issued Prime Medicine's second patent, No. 11,643,652, and allowed third patent application, No. 17/751,599 --

-- Cash, cash equivalents, investments and restricted cash balance of \$263.0 million as of March 31, 2023 --

Cambridge, Mass., May 11, 2023 – Prime Medicine, Inc. (Nasdaq: PRME), a biotechnology company committed to delivering a new class of differentiated one-time curative genetic therapies, today reported financial results and provided business updates for the first quarter ended March 31, 2023.

“The first quarter and recent months were marked by a number of important milestones across our business as we execute against our mission of delivering a new class of one-time, potentially curative genetic therapies,” said Keith Gottesdiener, M.D., President and Chief Executive Officer of Prime Medicine. “We are particularly encouraged by recent progress across our diversified pipeline. Earlier this year, we nominated our first development candidate, PM359, and, at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting in May, we will showcase new preclinical data further supporting the potential of PM359 to correct the causative mutation of chronic granulomatous disease (CGD). Also at ASGCT, we will share new data demonstrating the power of our PASSIGE™ technology to generate CAR-T cells, potentially unlocking the opportunity for Prime Editing to address a number of cancers and immune diseases. Together, these presentations underscore our belief that Prime Editing is unrivaled in its breadth and potential to offer curative treatments for many diseases.”

Dr. Gottesdiener continued, “Additionally, we recently strengthened our corporate position with additions to our intellectual property portfolio. The recent patent issuance and patent application allowance mark a significant step toward our goal of securing the broadest intellectual property protection for our platform technology. We are also pleased to announce the appointment of Jeff Marrazzo to our Board of Directors. With his experience as co-founder and former Chief Executive Officer of a commercial gene therapy company, Jeff brings expertise and a unique perspective that we believe will complement the skills of our leadership team. We look forward to partnering with him as we pursue our shared vision of pushing the frontier of genetic medicine to deliver better outcomes to patients.”

Recent Business Updates

Pipeline

- Today, Prime Medicine announced that it will present preclinical data from its Prime Editing platform at the ASGCT 26th Annual Meeting, being held May 16-20, 2023 in Los Angeles. In an oral presentation, Prime Medicine will highlight new findings further demonstrating the potential of Prime Editing to correct the causative mutation of CGD and, in a poster presentation, will showcase the potential of the PASSIGE platform to multiplex edit CAR-T cells for the treatment of certain cancers and immune diseases. Details of the presentations are as follows:

Abstract Title: (101) Prime Editing of Human CD34+ Long-Term Hematopoietic Stem Cells Precisely Corrects the Causative Mutation of p47phox Chronic Granulomatous Disease and Restores NADPH Oxidase Activity in Myeloid Progeny

Date & Time: Wednesday, May 17, 2023, 5:15 – 5:30 p.m. PT

Room: Room 515 AB

Session Title: Genome Editing Therapies & Safety I

Presenter: Jennifer Gori

Abstract Title: (602) An All-Prime Editing One-Step Approach for Non-Viral Generation of a Multiplex-Edited Allogeneic CAR-T Cell Product

Date & Time: Wednesday, May 17, 2023, 12:00 p.m. PT

Session Title: Wednesday Poster Session

Presenter: Emily Pomeroy

Corporate

- In May 2023, Prime Medicine appointed Jeff Marrazzo, co-founder and former Chief Executive Officer of Spark Therapeutics, Inc., to its Board of Directors. Jeff founded and built Spark Therapeutics from an idea incubated within the Children's Hospital of Philadelphia (CHOP) into the world's first fully integrated, commercial gene therapy company with over 850 employees at the time of his departure. Under Jeff's leadership, Spark developed and launched LUXTURNA® for a rare blinding disorder, the first U.S. Food and Drug Administration-approved gene therapy for a genetic disease in the U.S., spearheading the creation of novel reimbursement models to ensure patient access to genetic medicines. While at Spark, Jeff shepherded multiple gene therapies into the clinic for patients with conditions ranging from inherited retinal diseases to rare bleeding and neuromuscular disorders, raising \$1 billion in capital and establishing major partnerships with Pfizer and Novartis. Jeff's orchestration of Spark's \$4.8 billion sale to Roche in 2019 marked a 100-fold increase in the company's market value over six years.
- In May 2023, the U.S. Patent and Trademark Office (PTO) issued Prime Medicine's second patent, No. 11,643,652, which covers composition of matter for Prime Editor guide RNAs (PEgRNAs). In April 2023, Prime Medicine received a notice of allowance from the U.S. PTO for its third patent application, No. 17/751,599, which covers Prime Editing systems that include a PEgRNA, Prime Editor protein, and, optionally, a recombinase.

Anticipated Upcoming Milestones

Prime Medicine expects the following activities and next steps to drive the Prime Editing platform forward:

Pipeline

- Initiate investigational new drug (IND)-enabling studies for PM359 in CGD in 2023.
- Expand preclinical proof-of-concept *in vivo* data, with plans to share data from *in vivo* rodent studies and large animal studies from several programs in the second half of 2023.
- Share *in vitro* preclinical data in additional liver, eye and neuromuscular programs.
- Complete first IND filing as early as 2024 and additional IND filings anticipated in 2025.

Platform

- Continue to develop and optimize non-viral and viral delivery systems and share additional proof-of-concept data from *in vivo* rodent and large animal studies in the second half of 2023.
- Further demonstrate superior off-target profiles for Prime Editing programs.
- Expand Prime Editing using proprietary recombinase and/or retrotransposon technologies for new and existing programs.
- Maximize Prime Editing's broad therapeutic potential and create value through strategic business development that extends the reach and impact of Prime Editing to areas beyond Prime Medicine's current areas of focus.

First Quarter 2023 Financial Results:

- **R&D Expenses:** Research and development (R&D) expenses were \$30.9 million for the three months ended March 31, 2023, as compared to \$13.7 million for the three months ended March 31, 2022. This increase was primarily due to increases in lab supplies, personnel, and facilities costs as the company continues to expand and build out its R&D activities and function.
- **G&A Expenses:** General and administrative (G&A) expenses were \$9.2 million for the three months ended March 31, 2023, as compared to \$6.2 million for the three months ended March 31, 2022. This increase was

primarily due to an increase in facility costs and professional costs primarily attributable to the build-out of the company's G&A team to support business growth.

- **Net Loss:** Net loss was \$39.4 million for the three months ended March 31, 2023, as compared to \$23.8 million for the three months ended March 31, 2022.
- **Cash Position:** As of March 31, 2023, cash, cash equivalents, investments and restricted cash were \$263.0 million, as compared to \$307.4 million as of December 31, 2022.

Financial Guidance

Based on its current operating plans, Prime Medicine expects that its cash, cash equivalents and investments as of March 31, 2023 will be sufficient to fund its anticipated operating expenses and capital expenditure requirements into 2025.

About Prime Medicine

Prime Medicine is a leading biotechnology company dedicated to creating and delivering the next generation of gene editing therapies to patients. The Company is leveraging its proprietary Prime Editing platform, a versatile, precise and efficient gene editing technology, to develop a new class of differentiated, one-time, potentially curative genetic therapies. Designed to make only the right edit at the right position within a gene while minimizing unwanted DNA modifications, Prime Editors have the potential to repair almost all types of genetic mutations and work in many different tissues, organs and cell types.

Prime Medicine is currently progressing a diversified portfolio of eighteen programs initially focused on genetic diseases with a fast, direct path to treating patients or with a high unmet need because they cannot be treated using other gene-editing approaches. Over time, the Company intends to maximize Prime Editing's therapeutic potential and advance potentially curative therapeutic options to patients for a broad spectrum of diseases. For more information, please visit www.primemedicine.com.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements about Prime Medicine's beliefs and expectations regarding: the initiation, timing, progress, and results of its research and development programs, preclinical studies and future clinical trials, and the release of data related thereto, including the initiation of IND-enabling studies for PM359, the potential of PM359 to correct the causative mutation of CGD, and the capacity of its PASSIGE technology to edit CAR-T cells for the treatment of certain cancers and immune diseases; its ability to advance its portfolio toward additional preclinical proof-of-concept readouts; its ability to demonstrate, and the timing of, preclinical proof-of-concept in vivo for multiple programs; its development and optimization of various non-viral and viral delivery systems; its ability to demonstrate superior off-target profiles for Prime Editing programs; its expansion of Prime Editing using proprietary recombinase and/or retrotransposon and other proprietary technologies; the expansion of Prime Editing's therapeutic potential and the creation of value through strategic business development to extend the reach and impact of Prime Editing to areas beyond Prime Medicine's current areas of focus; its expectations regarding the breadth and potential to offer curative treatments for disease-causing genetic mutations; the timing of its regulatory filings, including its anticipated initial IND submission as early as 2024 with additional filings anticipated in 2025; the implementation of its strategic plans for its business, programs, and technology; and its estimates of expenses, capital requirements, and needs for additional financing and its expectations regarding the ability to fund its anticipated operating expenses and capital expenditure requirements into 2025. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to

differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: uncertainties related to the authorization, initiation, and conduct of preclinical and other development requirements for potential product candidates, including uncertainties related to regulatory approvals; risks related to the development and optimization of new technologies, the results of preclinical studies, or clinical studies not being predictive of future results in connection with future studies; the scope of protection Prime Medicine is able to establish and maintain for intellectual property rights covering its Prime Editing technology; Prime Medicine's ability to identify and enter into future license agreements and collaborations; and general economic, industry and market conditions, including rising interest rates, inflation, and adverse developments affecting the financial services industry. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Prime Medicine's most recent Annual Report on Form 10-K, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Prime Medicine's views only as of today and should not be relied upon as representing its views as of any subsequent date. Prime Medicine explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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**Condensed Consolidated Balance Sheet Data
(unaudited)**

(in thousands)	March 31, 2023	December 31, 2022
Cash, cash equivalents and investments	\$ 249,518	\$ 293,921
Total assets	316,946	360,314
Total liabilities	38,145	44,044
Total stockholders' equity	278,801	316,270

**Condensed Consolidated Statement of Operations
(unaudited)**

(in thousands, except share and per share amounts)	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 30,880	\$ 13,677
General and administrative	9,153	6,221
Total operating expenses	40,033	19,898
Loss from operations	(40,033)	(19,898)
Other income (expense):		
Change in fair value of short-term investment — related party	(1,701)	(4,485)
Other income, net	2,135	11
Total other income (expense), net	434	(4,474)
Net loss before income taxes	(39,599)	(24,372)
Benefit from income taxes	(202)	(532)
Net loss	\$ (39,397)	\$ (23,840)
Cumulative dividend on preferred stock	—	(6,224)
Net loss attributable to common stockholders	\$ (39,397)	\$ (30,064)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (1.58)
Weighted-average common shares outstanding, basic and diluted	89,064,895	19,050,385