

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

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**FORM 8-K**

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

**March 1, 2024  
Date of Report (Date of earliest event reported)**

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

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**Delaware  
(State or other jurisdiction of  
incorporation)  
21 Erie Street  
Cambridge, MA  
(Address of principal executive offices)**

**001-41536  
(Commission File Number)**

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

**02139  
(Zip Code)**

**(617) 564-0013  
(Registrant's telephone number, including area code)**

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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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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.

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**Item 2.02 Results of Operations and Financial Condition.**

On March 1, 2024, Prime Medicine, Inc. (the “Company”) issued a press release announcing its financial results and business highlights for the quarter and fiscal year ended December 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, including 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	<a href="#">Press Release, dated March 1, 2024, furnished herewith.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 1, 2024

Prime Medicine, Inc.

By: /s/ Keith Gottesdiener

Name: Keith Gottesdiener, M.D.

Title: President and Chief Executive Officer



## Prime Medicine Reports Full Year 2023 Financial Results and Provides Business Updates

-- Maturing into clinical-stage company; on-track to file IND application or CTA for PM359 in 1H 2024, with initial data expected in 2025 --

-- Progressing broader portfolio across core areas of focus; expect to initiate IND-enabling activities in first liver and ocular disease programs in 2024 --

-- Advancing hotspot and PASSIGE™ Prime Editors for CF following entry into therapeutic development agreement with Cystic Fibrosis Foundation --

-- Completed upsized \$161 million public offering --

**Cambridge, Mass.**, March 1, 2024 – 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 for the full year ended December 31, 2023 and provided a business update.

“In 2024, we anticipate undergoing a significant transformation, maturing into a clinical-stage company and bringing the first-ever Prime Editing-based therapeutic candidate to patients. We look forward to filing our first IND or CTA in the months ahead, and to commencing our Phase 1 clinical trial in CGD, a serious, life-threatening disease that we believe is uniquely suited for treatment with a Prime Editing-based approach,” said Keith Gottesdiener, M.D., President and Chief Executive Officer of Prime Medicine. “In parallel, we continue to progress our broader pipeline, where we are advancing programs across our core areas of focus: hematology and immunology, liver, lung, ocular and neuromuscular disease. This year, we expect to advance our first liver and ocular disease programs into IND-enabling studies, while continuing to explore business development opportunities that can accelerate our existing work, enable us to pursue additional programs, and provide access to innovation that can further advance Prime Editing. Over time, we believe the modularity of the Prime Editing platform will allow us to quickly build on our current efforts, unlocking opportunities across a wide range of genetic and common diseases, which collectively impact millions of people.”

### Recent Business Updates

#### *Chronic Granulomatous Disease (CGD)*

- In January 2024, Prime Medicine received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for PM359.

#### *Cystic Fibrosis (CF)*

- In January 2024, Prime Medicine announced that the Cystic Fibrosis Foundation (CF Foundation) agreed to provide the Company with up to \$15 million to support the development of Prime Editors for the treatment of CF. This funding will allow Prime Medicine to progress two distinct strategies for applying Prime Editing to treat CF: hotspot editing and PASSIGE™ (Prime Assisted Site Specific Integrase Gene Editing).

### Corporate

- In February 2024, the U.S. Patent and Trademark Office issued Prime Medicine’s fourth U.S. patent, No. 11,912,985, “Methods and Compositions for Simultaneous Editing of Both Strands of a Target Double-Stranded Nucleotide Sequence,” which covers dual flap Prime Editing systems.
- In February 2024, Prime Medicine closed an upsized underwritten public offering of common stock at a public offering price of \$6.25 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase shares of common stock, at a public offering price of \$6.24999 per pre-funded warrant. Gross proceeds to Prime Medicine from the offering, before deducting underwriting discounts and commissions and offering expenses, were approximately \$161.0 million.



- In January 2024, Prime Medicine announced the appointment of Allan Reine, M.D., as the Company's Chief Financial Officer. Dr. Reine, a seasoned financial executive with over twenty years' experience in the biotechnology industry, will be responsible for the company's financing strategy and investor relations, and will oversee all financial operations.

### Anticipated Upcoming Milestones

Prime Medicine expects the following activities and next steps to drive Prime Medicine forward and support the company's maturation into a clinical-stage company:

#### *Hematology and Immunology*

- Open investigational new drug (IND) application and/or clinical trial application (CTA) for Phase 1/2 study in CGD in the first half of 2024, with initial clinical data anticipated in 2025.
- Advance Shielded Hematopoietic Stem Cell (HSC) and Immunotherapy Pairs (SCIP) technology, establish proof-of-concept in HSC and immunotherapy and identify first clinical program(s) with this approach in 2024.
- Advance differentiated CAR-T program, using PASSIGE technology, into lead optimization.

#### *Liver:*

- Continue to advance preclinical studies for three liver programs and initiate IND-enabling activities for at least one in 2024, leading to an IND and/or CTA in the second half of 2025 or first half of 2026.

#### *Ocular:*

- Nominate development candidate for Retinitis Pigmentosa/Rhodopsin (RHO) and initiate IND-enabling activities in 2024.

#### *Neuromuscular:*

- Continue to advance Friedreich's Ataxia and advance one other program into lead optimization in 2024.
- In large animal studies, establish adeno-associated virus (AAV) delivery platform and route of administration for neuromuscular programs in 2024.

### Full Year 2023 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were \$147.9 million for the year ended December 31, 2023, as compared to \$86.7 million for the year ended December 31, 2022. The increase in R&D expenses was driven by IND-enabling activities for the Company's CGD program and expenses related to the advancement of the company's pipeline and platform.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$43.4 million for the year ended December 31, 2023, as compared to \$29.8 million for the year ended December 31, 2022.
- **Net Loss:** Net loss was \$198.1 million for the year ended December 31, 2023, as compared to \$121.8 million for the year ended December 31, 2022. Part of the increase was attributable to a one-time charge for the Company's settlement with Myeloid Therapeutics, Inc.
- **Cash Position:** As of December 31, 2023, cash, cash equivalents, investments and restricted cash were \$135.2 million, as compared to \$307.4 million as of December 31, 2022.

### 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 deploying its proprietary Prime Editing platform, a versatile, precise and efficient gene editing technology, to develop a new class of differentiated one-time 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. Taken together, Prime Editing's versatile gene editing capabilities could unlock opportunities across thousands of potential indications.

Prime Medicine is currently progressing a diversified portfolio of investigational therapeutic programs organized around core areas of focus: hematology and immunology, liver, lung, ocular and neuromuscular. Across each core area, Prime Medicine's initial focus is on genetic diseases with a fast, direct path to treating patients, and those with high unmet need not currently addressable using other gene editing approaches. Over time, the Company intends to maximize Prime Editing's broad and versatile therapeutic potential to expand beyond the genetic diseases in its initial pipeline, potentially including immunological diseases, cancers, infectious diseases, and targeting genetic risk factors in common diseases, which collectively impact millions of people. For more information, please visit [www.primemedicine.com](http://www.primemedicine.com).

### **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; the anticipated maturation into a clinical-stage company and bringing the first-ever Prime Editing-based therapeutic candidate to patients; progressing its broader pipeline across core areas of focus; exploring business development opportunities that could accelerate existing work and the benefits thereof; the modularity of the Prime Editing platform and the benefits thereof; certain activities and next steps to support the company's maturation into a clinical-stage company, including opening IND and/or CTA applications, clinical data expectations, establishing proof of concept, advancing programs into lead optimization, advancing preclinical studies and initiating IND-enabling activities, nominating development candidates, and establishing delivery platform and route of administration; its expectations regarding the breadth of Prime Editing technology and the implementation of its strategic plans for its business, programs, and technology; and the potential of Prime Editing to unlock opportunities across thousands of potential indications. 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 an IND or CTA filing and entering clinical trials; the authorization, initiation, and conduct of preclinical and IND-enabling studies and other development requirements for potential product candidates, including uncertainties related to opening INDs and obtaining 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 subject to any obligations under applicable law. 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)	December 31,	
	2023	2022
Cash, cash equivalents, and investments	\$ 121,665	\$ 293,921
Total assets	\$ 193,851	\$ 360,314
Total liabilities	\$ 60,780	\$ 44,044
Total stockholders' equity	\$ 133,071	\$ 316,270

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

(in thousands, except share and per share amounts)	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 147,905	\$ 86,725
Settlement payment — related party	13,500	—
General and administrative	43,387	29,819
Total operating expenses	204,792	116,544
Loss from operations	(204,792)	(116,544)
Other income (expense):		
Change in fair value of short-term investment — related party	(2,382)	(8,128)
Other income, net	8,762	1,903
Total other income (expense), net	6,380	(6,225)
Net loss before income taxes	(198,412)	(122,769)
Benefit from income taxes	279	948
Net loss	(198,133)	(121,821)
Cumulative dividend on preferred stock	—	(20,193)
Net loss attributable to common stockholders	\$ (198,133)	\$ (142,014)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.18)	\$ (4.19)
Weighted-average common shares outstanding, basic and diluted	90,969,327	33,891,264