UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

| | | washington, D.C. 2034) | | | | | |
|--------|--|--|--|--|--|--|--|
| | | FORM 8-K | | | | | |
| | | CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 | | | | | |
| | | August 8, 2024 Date of Report (Date of earliest event report | ed) | | | | |
| | | Prime Medicine, Inc. (Exact name of registrant as specified in its cha | arter) | | | | |
| | Delaware (State or other jurisdiction of incorporation) | 001-41536 (Commission File Number) | 84-3097762 (I.R.S. Employer Identification No.) | | | | |
| | 60 First Street Cambridge, MA | | 02141 | | | | |
| | (Address of principal executive offices) | | (Zip Code) | | | | |
| | | (617) 564-0013 | | | | | |
| | | C filing is intended to simultaneously satisfy the fili | ng obligation of the registrant under any of the | | | | |
| Tollov | wing provisions: Written communications pursuant to Re | ule 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 p | ursuant to Rule 14d-2(b) under the Exchange Act (1 | 7 CFR 240.14d-2(b)) | | | | |
| | Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) | | | | | | |
| Secu | rities registered pursuant to Section 12(b) o | f the Act: | | | | | |
| | Title of each class | Trading Symbol(s) | Name of each exchange on which registered | | | | |
| С | ommon stock, par value \$.00001 per share | PRME | The Nasdaq Global Market | | | | |
| | ate by check mark whether the registrant is ter) or Rule12b-2 of the Securities Exchange | an emerging growth company as defined in Rule 40 e Act of 1934 (§250.12b-2 of this chapter). | 05 of the Securities Act of 1933 (§230.405 of this | | | | |
| Emer | ging growth company 🗵 | | | | | | |
| | | ck mark if the registrant has elected not to use the e | xtended transition period for complying with any new | | | | |

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2024, Prime Medicine, Inc. (the "Company") issued a press release announcing its financial results and business highlights for the quarter ended June 30, 2024. 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 | Press Release, dated August 8, 2024, furnished herewith. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |
| | |
| | |

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: August 8, 2024

Prime Medicine, Inc.

By:

/s/ Keith Gottesdiener

Name:

Keith Gottesdiener, M.D.

Title:

President and Chief Executive Officer



Prime Medicine Reports Second Quarter 2024 Financial Results and Provides Business Updates

Cambridge, Mass., August 8, 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 second quarter ended June 30, 2024, and provided a business update.

"In the second quarter, we achieved a key milestone for Prime Medicine and our next-generation gene editing technology, securing clearance from the U.S. Food and Drug Administration (FDA) to advance PM359, our Prime Editor for the treatment of chronic granulomatous disease (CGD), into the clinic. We are now in the process of initiating our Phase 1/2 clinical trial, and we look forward to sharing initial clinical data in 2025," said Keith Gottesdiener, M.D., President and Chief Executive Officer of Prime Medicine. "As we mature into a clinical-stage company, I am particularly excited to announce Dr. Mohammed Asmal's promotion to Chief Medical Officer. Since joining Prime Medicine in 2022, Mohammed has been a valuable member of our leadership team, helping shepherd PM359 to an investigational new drug (IND) acceptance and Prime's first clinical trial, and leading our clinical development strategy across our portfolio more broadly. I look forward to his continued contributions as we prepare to dose the first patient with a Prime Editor."

Dr. Gottesdiener continued, "In addition, we are advancing multiple programs across our core areas of focus, and we look forward to sharing new preclinical data showcasing our proprietary delivery capabilities, as well as the safety and potential of our Prime Editing technology across target tissues in the coming months. Importantly, we believe the modularity of our Prime Editing platform will allow us to apply learnings from these efforts across our portfolio, accelerating and de-risking our ongoing work and longer-term, enabling us to more efficiently execute our clinical development plans with the hope of rapidly impacting millions of people."

Recent Business Updates

Corporate

 Today, Prime Medicine announced the promotion of Mohammed Asmal, M.D, Ph.D. to Chief Medical Officer, effective immediately. Dr. Asmal has served as Senior Vice President, Head of Clinical at Prime Medicine since 2022.

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:

- Announce initial clinical data from the Phase 1/2 clinical trial of PM359 in CGD 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 Prime Assisted Site-Specific Integrase Gene Editing (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 clinical trial application (CTA) in the second half of 2025 or first half of 2026.



Ocular:

Nominate development candidate for Retinitis Pigmentosa/Rhodopsin (RHO-RP) program 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

Second Quarter 2024 Financial Results

- Research and Development (R&D) Expenses: R&D expenses were \$43.1 million for the three months ended June 30, 2024, as compared to \$34.6 million for the three months ended June 30, 2023. The increase in R&D expenses was driven by expenses related to the advancement of the Company's pipeline and platform.
- General and Administrative (G&A) Expenses: G&A expenses were \$12.6 million for the three months ended June 30, 2024, as compared to \$10.7 million for the three months ended June 30, 2023.
- Net Loss: Net loss was \$55.3 million for the three months ended June 30, 2024, as compared to \$42.4 million for the three months ended June 30, 2023
- Cash Position: As of June 30, 2024, cash, cash equivalents, investments, and restricted cash were \$176.4 million, as compared to \$135.2 million as of December 31, 2023.

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.

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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 potential of PM359 to correct the causative mutation of CGD; the anticipated maturation into a clinical-stage company by bringing PM359 into clinical development in 2024 with



initial clinical data from the planned Phase 1/2 clinical trial of PM359 expected in 2025; 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 potential for Prime Editors to repair genetic mutations and offer curative genetic therapies for a wide spectrum of diseases; the potential of Prime Editors to reproducibly correct disease-causing genetic mutations across different tissues, organs and cell types, and the capacity of its PASSIGE technology to edit CAR-T cells for the treatment of certain cancers and immune diseases; certain activities and next steps to support the Company's maturation into a clinical-stage company, including opening an IND and/or CTA application, clinical data expectations, establishing proof-of-concept, advancing programs into lead optimization, advancing preclinical studies and initiating IND-enabling activities, nominating development candidate, and establishing AAV delivery platform and route of administration for neuromuscular programs; 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 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; 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," "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 Prime Medicine's product candidates 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; the effect of unfavorable macroeconomic conditions or market volatility resulting from general economic, industry and market conditions, including rising interest rates, inflation, and adverse developments affecting the financial services industry; and Prime Medicine's accumulated deficit and the expectation for continued operating losses and negative operating cash flows for the foreseeable future, including its expectations regarding the anticipated timeline of its cash runway and future financial performance. 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 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, 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.

Investor Contact

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Weighted-average common shares outstanding, basic and diluted

Condensed Consolidated Balance Sheet Data (unaudited)

| (in thousands) | June 3 2024 | ١, | December 31, 2023 |
|---|----------------|--------|----------------------|
| Cash, cash equivalents, and investments | \$ 1 | 62,868 | \$ 121,665 |
| Total assets | \$ 2 | 59,705 | \$ 193,851 |
| Total liabilities | \$ | 63,116 | \$ 60,780 |
| Total stockholders' equity | \$ 1 | 96.589 | \$ 133.071 |

Condensed Consolidated Statement of Operations (unaudited)

Three Months Ended June 30, 2024 2023 (in thousands, except share and per share amounts) Operating expenses: 43,071 \$ \$ 34,599 Research and development General and administrative 12,601 10,658 Total operating expenses 55,672 45,257 Loss from operations (55,672)(45,257)Other income (expense): Change in fair value of short-term investment — related party (1,925)263 2,136 2,640 Other income, net 211 2,903 Total other income (expense), net (55,461)(42,354)Net loss before income taxes (Provision for) benefit from income taxes 134 (31)(55,327)\$ (42,385)Net loss attributable to common stockholders \$ Net loss per share attributable to common stockholders, basic and diluted (0.46)\$ (0.47)119,188,866 90,467,298