

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

Date of Report (Date of earliest event reported): May 7, 2026

MONTE ROSA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40522
(Commission
File Number)

84-3766197
(I.R.S. Employer
Identification No.)

321 Harrison Avenue, Suite 900
Boston, MA 02118
(Address of principal executive offices, including zip code)

(617) 949-2643
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	GLUE	The Nasdaq Global Select 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 (§ 240.12b-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 7, 2026, Monte Rosa Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2026. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, 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

- | | |
|------|---|
| 99.1 | <u>Press Release issued by Monte Rosa Therapeutics, Inc. dated May 7, 2026.</u> |
| 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.

Monte Rosa Therapeutics, Inc.

Date: May 7, 2026

By: /s/ Markus Warmuth

Markus Warmuth

President and Chief Executive Officer

Monte Rosa Therapeutics Announces First Quarter 2026 Financial Results and Business Updates

Interim clinical data from GFORCE-1 trial of NEK7-directed MGD MRT-8102 demonstrated profound CRP reductions in subjects with elevated CVD risk; readout of expanded GFORCE-1 trial in subjects with elevated CVD risk anticipated in H2 2026

Company expects to initiate multiple MRT-8102 Phase 2 studies, including in patients with elevated atherosclerotic risk in H2 2026, in patients with gout flares in Q4 2026/Q1 2027, and in patients with moderate to severe hidradenitis suppurativa in H1 2027

Presented positive interim Phase 1/2 clinical data of GSPT1-directed MGD MRT-2359 in combination with an AR inhibitor in mCRPC patients with AR mutations; initiation of Phase 2 study evaluating MRT-2359 in combination with apalutamide in mCRPC patients with AR mutations planned for Q3 2026

VAV1-directed MGD MRT-6160 advancing toward anticipated initiation by Novartis of multiple Phase 2 studies in immune-mediated diseases

Preclinical data presented at AACR highlight a novel cyclin E1-directed MGD with superior selectivity and reduced off-target activity compared to CDK2 inhibitors; IND submission anticipated in H2 2026

Strong balance sheet with cash, cash equivalents, restricted cash, and marketable securities of \$671 million, expected to support operations into 2029

BOSTON, Mass., May 7, 2026 – [Monte Rosa Therapeutics, Inc.](#) (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today reported business highlights and financial results for the first quarter ended March 31, 2026.

“We continue to make excellent progress advancing multiple programs through the clinic, with all three of our clinical-stage programs approaching Phase 2 trial initiations,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “Building on interim clinical data for our NEK7-directed MGD MRT-8102 demonstrating rapid, deep, and durable reductions in systemic inflammation, we expect to read out the GFORCE-1 study in subjects with elevated cardiovascular disease (CVD) risk this year, and to initiate three Phase 2 studies, starting in H2 2026, in diseases driven by the NLRP3/IL-1/IL-6 pathway. We also expect our collaborator Novartis to initiate multiple Phase 2 studies of our VAV1-directed MGD MRT-6160 in immune-mediated diseases this year. In addition, our oncology programs are also progressing rapidly, in particular with a Phase 2 study initiation of MRT-2359 in metastatic castration-resistant prostate cancer (mCRPC) patients with androgen receptor (AR) mutations planned for Q3 2026, following the encouraging Phase 1/2 data we presented at ASCO GU.”

RECENT HIGHLIGHTS

MRT-8102, NEK7-directed MGD for inflammatory diseases driven by the NLRP3 inflammasome, IL-1, and IL-6

- In January, Monte Rosa announced positive interim data from an ongoing Phase 1 clinical study evaluating MRT-8102. In subjects with elevated CVD risk, after four weeks of MRT-8102 administration, CRP levels decreased by 85%, and 94% of study participants achieved CRP levels below 2 mg/L, a threshold associated with reduced CVD risk. The Company subsequently announced unblinded safety data from the single ascending dose / multiple ascending dose (SAD/MAD) cohorts and 3-month results from the ongoing long-term toxicology study in cynomolgus monkeys support a broad therapeutic index for MRT-8102.
- The ongoing GFORCE-1 study of MRT-8102 in subjects with elevated CVD risk is evaluating multiple dose levels to accelerate development in atherosclerotic cardiovascular disease (ASCVD) with an anticipated readout in H2 2026.
- Monte Rosa expects to initiate multiple Phase 2 studies of MRT-8102 in indications with high unmet need and strong biologic rationale for targeting the NLRP3/IL-1/IL-6 pathway:
 - A study (GFORCE-2) of MRT-8102 in patients with elevated atherosclerotic risk is expected to initiate in H2 2026 to evaluate the effect of MRT-8102 treatment for 12 weeks (plus open-label extension) on CRP levels, as well as effects on liver fat, liver inflammation, and obesity.
 - A study of MRT-8102 in patients with gout flares is expected to initiate in Q4 2026 or Q1 2027.
 - A study of MRT-8102 in patients with moderate to severe hidradenitis suppurativa is expected to initiate in H1 2027.

MRT-6160, VAV1-directed MGD for immune-mediated conditions

- Advancement of MRT-6160 toward multiple Phase 2 studies in immune-mediated diseases is ongoing, in collaboration with Novartis. Results from the Phase 1, single ascending dose / multiple ascending dose (SAD/MAD) study in healthy volunteers (clinicaltrials.gov identifier NCT06597799) support a clear path into anticipated Phase 2 studies and broad potential applications in multiple immune-mediated diseases.
- Monte Rosa has a global exclusive development and commercialization license agreement with Novartis to advance VAV1-directed MGDs, including MRT-6160. Monte Rosa is eligible to receive up to \$2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies. Novartis is responsible for conducting and funding Phase 2 studies. Monte Rosa will co-fund any Phase 3 clinical development and will share 30% of any profits and losses associated with the manufacturing and commercialization of MRT-6160 in the U.S., and is also eligible for tiered royalties on ex-U.S. net sales.

MRT-2359, GSPT1-directed MGD for metastatic CRPC

- In February, Monte Rosa presented additional interim data from an ongoing Phase 1/2 clinical study evaluating MRT-2359 in combination with enzalutamide in heavily pretreated patients with mCRPC at the ASCO Genitourinary Cancers Symposium (ASCO GU). MRT-2359 is an investigational, orally bioavailable, GSPT1-directed MGD. PSA responses in patients with AR mutations expanded to 5 of 5 patients, with a 100% disease control rate, including 2 patients with RECIST partial responses and 3 with stable disease, all showing reductions in size of target lesions. Across all 15 evaluable patients, the overall RECIST disease control rate was 67%, and 10 of 15 patients showed tumor size reductions of target lesions. The combination of MRT-2359 and enzalutamide was generally well-tolerated with primarily Grade 1-2 AEs. There were no treatment discontinuations due to AEs.
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- The Company plans to initiate a Phase 2 study (MODeFIRE-1) in 2026 of up to 25 patients to efficiently assess the efficacy of MRT-2359 in combination with the second-generation AR inhibitor apalutamide in mCRPC patients with AR mutations, with potential to expand the study into additional patient subsets.
- In March, Monte Rosa announced it entered into a supply agreement with Johnson & Johnson to evaluate MRT-2359 in combination with ERLEADA® (apalutamide) for the treatment of patients with mCRPC with androgen receptor (AR) mutations in its planned Phase 2 study.

Cyclin E1 (CCNE1)-directed MGD program for CCNE1-amplified solid tumors

- Monte Rosa presented preclinical data on the potential of its potent and highly selective cyclin E1 (CCNE1)-directed molecular glue degrader, MRT-55811, to treat CCNE1-amplified solid tumors at the American Association for Cancer Research (AACR) Annual Meeting 2026. MRT-55811 induced deep tumor regressions in CCNE1-amplified *in vivo* models of ovarian, breast, and gastric cancers, and demonstrated superior selectivity and reduced off-target activity compared to CDK2 inhibitors.
- Monte Rosa expects to submit an IND application for its CCNE1 MGD program in H2 2026. The Company expects to develop this molecule in ovarian cancer and other cancer types driven by CCNE1 amplification.

CDK2-directed MGD program for ER+ breast cancer

- Monte Rosa continues to advance its CDK2-directed MGD program for the treatment of ER+ breast cancer toward clinical development.

Corporate

- In January, Monte Rosa closed an upsized underwritten public offering. Gross proceeds, before deducting underwriting discounts and commissions and offering expenses, were \$345 million.
- Monte Rosa continues to progress its collaboration with Novartis to develop novel degraders for immune-mediated diseases and its collaboration with Roche to discover and develop MGDs against targets in cancer and neurological diseases previously considered impossible to drug.

ANTICIPATED UPCOMING MILESTONES AND DEVELOPMENT PRIORITIES

Immunology and Inflammation programs

- Readout of MRT-8102 GFORCE-1 study in subjects with elevated CVD risk anticipated in H2 2026.
- Initiate multiple Phase 2 studies of MRT-8102, including in elevated atherosclerotic risk patients in H2 2026, in gout flare patients in Q4 2026/Q1 2027, and in hidradenitis suppurativa patients in H1 2027.
- Submit an IND application for a second-generation NEK7-directed MGD in H2 2026.
- Monte Rosa expects its collaborator, Novartis, to initiate multiple Phase 2 studies of VAV1-directed MGD MRT-6160 in immune-mediated diseases in 2026.

Oncology programs

- Initiate the MODeFIRE-1 Phase 2 study of MRT-2359 in combination with apalutamide in mCRPC in Q3 2026.
- Submit an IND application for a cyclin E1-directed MGD in H2 2026.

FIRST QUARTER 2026 FINANCIAL RESULTS



Collaboration Revenue: Collaboration revenue for the first quarter of 2026 was \$4.2 million, compared to \$84.9 million for the first quarter of 2025. Collaboration revenue represents amounts earned from the Company's collaboration and license agreements with Roche and Novartis.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2026 were \$44.1 million, compared to \$32.2 million for the first quarter of 2025. These increases were driven by increased spending during the quarter on our MRT-8102 program and on other development and discovery programs.

General and Administrative (G&A) Expenses: G&A expenses for the first quarter of 2026 were \$10.2 million, compared to \$8.7 million for the first quarter of 2025. These increases, which include non-cash stock-based compensation, were driven by increased headcount and expenses in support of our growth and operations as a public company.

Net Loss: Net loss for the first quarter of 2026 was \$44.5 million, compared to \$46.9 million net income for the first quarter of 2025.

Cash Position and Financial Guidance:

Cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2026, were \$671.2 million, compared to cash, cash equivalents, restricted cash, and marketable securities of \$382.1 million as of December 31, 2025. The increase of \$289.1 million was primarily due to net proceeds from the underwritten public offering in January, partially offset by operational use of cash.

In January 2026, the Company closed an underwritten public equity offering of \$345.0 million aggregate gross proceeds. Aggregate net proceeds from the offering after deducting underwriting discounts and commissions and offering expenses were \$323.8 million.

Based on current cash, cash equivalents, restricted cash, and marketable securities, together with the proceeds from the January 2026 offering, the Company expects its cash and cash equivalents to be sufficient to fund planned operations and capital expenditures into 2029.

About Monte Rosa

Monte Rosa Therapeutics is a clinical-stage biotechnology company developing highly selective molecular glue degrader (MGD) medicines for patients living with serious diseases. MGDs are small molecule protein degraders that have the potential to treat many diseases that other modalities, including other degraders, cannot. Monte Rosa's QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) discovery engine combines AI-guided chemistry, diverse chemical libraries, structural biology, and proteomics to rationally design MGDs with unprecedented selectivity. Monte Rosa has developed the industry's leading pipeline of first-in-class and only-in-class MGDs, spanning autoimmune and inflammatory diseases, oncology, and beyond, with three programs in the clinic. Monte Rosa has ongoing collaborations with leading pharmaceutical companies in the areas of immunology, oncology, and neurology. For more information, visit www.monterosatx.com.

Forward-Looking Statements

This communication includes express and implied "forward-looking statements," including forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts and in some cases, can be identified by terms such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," or the negative of these

terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements contained herein include, but are not limited to, statements about our ability to grow our product pipeline, our ability to successfully complete research and further development and commercialization of our drug candidates in current or future indications, including the timing and results of our clinical trials and our ability to conduct and complete clinical trials, statements regarding our progress and speed of development of only-in-class and first-in-class molecular glue degrader therapeutics, statements around the Company's QuEEN™ discovery engine and the broad potential applications of the platform and the Company's ability to create long-term value through focused pipeline execution and strategic collaborations, as well as to expand the targetable protein space for MGD drug discovery, statements about the Company's view of its potential to rationally design MGDs with unprecedented selectivity, statements about the advancement and timeline of our preclinical and clinical programs, pipeline and the various products therein, including (i) the ongoing development of our VAV1-directed degrader, referred to as MRT-6160, statements related to its clear path into anticipated Phase 2 studies in collaboration with Novartis and our expectations regarding the broad potential applications in multiple immune-mediated diseases, as well as our expectation that our collaborator, Novartis, will initiate multiple Phase 2 studies of VAV1-directed MGD MRT-6160 in immune-mediated diseases in 2026, (ii) the ongoing development and progress of our NEK7-directed MGD, referred to as MRT-8102, including our expectations regarding anticipated readout of data of the GFORCE-1 study in subjects with elevated CVD risk in H2 2026, as well as our plans to target initiation of multiple Phase 2 studies of MRT-8102, including in elevated atherosclerotic risk patients in H2 2026, in gout flare patients in Q4 2026/Q1 2027, and in hidradenitis suppurativa patients in H1 2027, (iii) the ongoing development of a second-generation NEK7-directed MGD and our statements around targeted IND submission in H2 2026, (iv) our ongoing clinical development of MRT-2359, statements relating to our plans to target initiation of the MODeFIRE-1 Phase 2 study of MRT-2359 in combination with the second-generation androgen receptor inhibitor apalutamide in mCRPC in Q3 2026 and the potential to expand the study into additional patient subsets, (v) statements around the progress of both our CDK2 and cyclin E1-directed MGD programs, including statements around the targeted timing of submission of an IND application in H2 2026 for a cyclin E1-directed MGD, and statements regarding the expected potential clinical benefit of MRT-55811 in CCNE1-amplified solid tumors, as well as statements related to the expected potential clinical benefit of any of our candidates, advancement and application of our platform, statements around our ability to capitalize on and potential benefits resulting from our research and translational insights, including announcements related to preclinical programs, as well as our ability to optimize collaborations with industry partners on our development programs, including our collaborations with Novartis and Roche, statements about obligations under our collaboration agreements, expectations around the receipt of any payments under such agreements and the future studies, development and commercialization of various products, statements regarding regulatory filings for our development programs, including the planned timing of such regulatory filings, such as IND applications, and potential review by regulatory authorities, our use of capital, expenses and other financial results in the future, availability of funding for existing programs through multiple anticipated Phase 2 study initiations and clinical data readouts, ability to fund operations and capital expenditures into 2029, as well as our expectations of success for our programs, strength of collaboration relationships and the strength of our financial position, among others. By their nature, these statements are subject to numerous risks and uncertainties, including those risks and uncertainties set forth in our most recent Annual Report on Form 10-K for the year ended December 31, 2025, filed with the U.S. Securities and Exchange Commission on March 17, 2026, and any subsequent filings, that could cause actual results, performance or achievement to differ materially and adversely from those anticipated or implied in the statements. You should not rely upon forward-looking statements as predictions of future events. Although our management believes that

the expectations reflected in our statements are reasonable, we cannot guarantee that the future results, performance, or events and circumstances described in the forward-looking statements will be achieved or occur. Recipients are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date such statements are made and should not be construed as statements of fact. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, any future presentations, or otherwise, except as required by applicable law. Certain information contained in these materials and any statements made orally during any presentation of these materials that relate to the materials or are based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party studies, publications, surveys and other data to be reliable as of the date of these materials, we have not independently verified, and make no representations as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of our internal estimates or research and no reliance should be made on any information or statements made in these materials relating to or based on such internal estimates and research.

Condensed Consolidated Balance Sheets
(in thousands, except share amounts)
(unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 159,859	\$ 129,883
Marketable securities	506,361	247,221
Collaboration receivable	—	7,000
Other receivables	4,609	4,600
Prepaid expenses and other current assets	6,718	4,481
Total current assets	677,547	393,185
Property and equipment, net	28,409	25,986
Operating lease right-of-use assets	24,693	24,386
Restricted cash	4,947	4,954
Other long-term assets	832	148
Total assets	\$ 736,428	\$ 448,659
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 7,900	\$ 3,550
Accrued expenses and other current liabilities	25,594	26,694
Current deferred revenue	33,059	29,571
Current portion of operating lease liability	4,483	4,397
Total current liabilities	71,036	64,212
Deferred revenue, net of current	103,635	111,332
Defined benefit plan liability	5,260	5,265
Operating lease liability	34,581	34,794
Total liabilities	214,512	215,603
Stockholders' equity		
Common stock, \$0.0001 par value; 500,000,000 shares authorized, 84,321,705 and 65,543,723 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	8	7
Additional paid-in capital	1,048,371	714,090
Accumulated other comprehensive loss	(4,746)	(3,827)
Accumulated deficit	(521,717)	(477,214)
Total stockholders' equity	521,916	233,056
Total liabilities and stockholders' equity	\$ 736,428	\$ 448,659

Condensed Consolidated Statement of Operations
(in thousands)
(unaudited)

	Three months ended March 31,			
	2026		2025	
Collaboration revenue	\$	4,210	\$	84,929
Operating expenses:				
Research and development		44,069	\$	32,190
General and administrative		10,175		8,703
Total operating expenses		54,244		40,893
(Loss) income from operations		(50,034)		44,036
Other income:				
Interest income		5,591		3,439
Foreign currency exchange (loss) gain		(8)		173
Gain on disposal of property and equipment		—		59
Total other income		5,583		3,671
Net (loss) income before income taxes	\$	(44,451)	\$	47,707
Income tax provision		(52)		(822)
Net (loss) income	\$	(44,503)	\$	46,885

Investors

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