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): August 7, 2025

MONTE ROSA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-40522**	**84-3766197**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 August 7, 2025, Monte Rosa Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2025. 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	Press Release issued by Monte Rosa Therapeutics, Inc. dated August 7, 2025.
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.

Monte Rosa Therapeutics, Inc.

Date: August 7, 2025

By: /s/ Markus Warmuth
Markus Warmuth
President and Chief Executive Officer

Monte Rosa Therapeutics Announces Second Quarter 2025 Financial Results and Business Updates

Phase 1 study of NEK7-directed molecular glue degrader (MGD) MRT-8102 underway, to investigate a potential novel therapeutic approach for treating inflammatory diseases driven by the NLRP3 inflammasome; initial readout anticipated in H1 2026

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

Phase 1/2 study of GSPT1-directed MGD MRT-2359 advancing in heavily pretreated, castration-resistant prostate cancer patients; additional results on track for H2 2025

Strong cash position expected to fund operations into 2028 through multiple anticipated proof-of-concept clinical readouts

BOSTON, Mass., Aug. 7, 2025 – 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 second quarter ended June 30, 2025.

“With the advancement of our third program into clinical development, we continue to efficiently execute across our portfolio of only-in-class and first-in-class molecular glue degraders,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “We have now dosed the initial single ascending dose (SAD) cohort in our Phase 1 study of MRT-8102, the only clinical-stage MGD that selectively degrades NEK7. Based on the potency, selectivity, and durable pharmacodynamics seen in our preclinical studies, we believe MRT-8102 offers a highly differentiated approach to potentially address a wide range of inflammatory and cardio-immunology indications driven by the NLRP3 inflammasome, IL-1β and IL-6. The execution of this program builds on the experience and success of our Phase 1 study for MRT-6160, our MGD directed against VAV1. We continue, in collaboration with Novartis, to progress MRT-6160 towards a broad development program of multiple well-powered Phase 2 studies in immune-mediated diseases, building on our highly encouraging Phase 1 clinical data disclosed earlier this year. In oncology, we continue to evaluate MRT-2359 in castration-resistant prostate cancer and are on track to report additional clinical data later this year. We also eagerly anticipate a development candidate (DC) nomination this year and IND submission next year for one or both of our cell cycle programs directed at CCNE1 and CDK2, two well-validated tumor drivers poorly addressed by conventional approaches.”

Dr. Warmuth continued**, “**In parallel with the progress made with our clinical programs, we were proud to see fundamental results from our QuEEN™ discovery engine featured in *Science,* highlighting Monte Rosa’s leadership applying proprietary AI/ML techniques to the discovery of molecular glue degraders, dramatically expanding the addressable protein target space as well as the chemical space for MGDs to address these targets. These advances underscore the broad potential applications of the platform and our ability to create long-term value through focused pipeline execution and strategic collaborations.”

RECENT HIGHLIGHTS

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

- In July 2025, Monte Rosa dosed the first subjects in a Phase 1 study of MRT-8102, a first-in-class, NEK7-directed MGD for inflammatory diseases driven by the NLRP3 inflammasome, IL-1β, and IL-6. The ongoing study includes SAD/MAD cohorts in healthy volunteers and an additional cohort designed to evaluate potential early proof of concept in subjects with increased cardiovascular disease (CVD) risk and elevated C-reactive protein (CRP). Initial data are expected in H1 2026.

MRT-2359, GSPT1-directed MGD for MYC-driven solid tumors

- Monte Rosa continues to enroll and evaluate MRT-2359 in patients with castration-resistant prostate cancer (CRPC), with the potential to expand enrollment to 20-30 patients if a positive efficacy signal continues to be observed. The Company expects to present additional results in H2 2025. Monte Rosa is also assessing activity in patients with hormone receptor (HR)+ breast cancer and expects to present results for this cohort in H2 2025.

Cyclin E1 and CDK2-directed MGD programs for treatment of solid tumors

- In April 2025, Monte Rosa presented preclinical data on the potential of its highly selective CDK2-directed molecular glue degrader, MRT-51443, to treat HR-positive/HER2-negative breast cancer at the American Association for Cancer Research (AACR) Annual Meeting 2025.

QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) discovery engine

- In July 2025, Monte Rosa's publication in Science showcased the Company's QuEEN™ AI/ML-powered degrader discovery engine. The findings significantly expand the targetable protein space for MGD drug discovery, unlocking new opportunities to address previously undruggable therapeutic targets.

ANTICIPATED UPCOMING MILESTONES AND DEVELOPMENT PRIORITIES

- Continue advancement of MRT-6160 toward Phase 2 initiation, in collaboration with Novartis.
- Share MRT-8102 Phase 1 results in H1 2026.
- Submit an IND application for the second-generation NEK7-directed MGD with enhanced CNS penetration in 2026.

- Share additional MRT-2359 Phase 1/2 study data in heavily pretreated CRPC patients and in patients with HR+ breast cancer in H2 2025.
- Nominate a development candidate for a CDK2 and/or cyclin E1-directed MGD in H2 2025 and submit an IND application in 2026

SECOND QUARTER 2025 FINANCIAL RESULTS

Collaboration revenue: Collaboration revenue for the second quarter of 2025 was $23.2 million, compared to $4.7 million for the quarter ended June 30, 2024. Collaboration revenue represents amounts earned from our collaboration and license agreements with Roche and Novartis, primarily revenue recognized from the Novartis $150 million upfront payment in the fourth quarter of 2024 based on progress made on our performance obligations defined in the Novartis License Agreement.

Research and Development (R&D) Expenses: R&D expenses for the second quarter of 2025 were $30.7 million, compared to $28.1 million for the second quarter of 2024. These increases were driven by the successful achievement of key milestones in our R&D organization, including the continuation of the MRT-2359 clinical study, continued program activities for MRT-6160 in preparation for Phase 2 studies, the advancement of MRT-8102 to enter the clinic, the progression of our preclinical pipeline, including research performed in connection with our collaboration with Roche, and the continued development of the Company's QuEEN™ discovery engine. Non-cash stock-based compensation constituted $2.9 million of R&D expenses for Q2 2025, compared to $2.6 million in the same period in 2024.

General and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2025 were $8.1 million compared to $9.3 million for the second quarter of 2024. G&A expenses included non-cash stock-based compensation of $2.0 million for the second quarter of 2025, compared to $1.9 million in the same period in 2024.

Net Loss: Net loss for the second quarter of 2025 was $12.3 million, compared to a net loss of $30.3 million for the second quarter of 2024.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of June 30, 2025, were $295.5 million, compared to cash, cash equivalents, restricted cash, and marketable securities of $331.0 million as of March 31, 2025. The decrease of $35.5 million was primarily due to the operational use of cash.

Based on current cash, cash equivalents, restricted cash, marketable securities, and certain anticipated Roche collaboration revenue, the Company expects its cash and cash equivalents to be sufficient to fund planned operations and capital expenditures into 2028.

About MRT-6160
MRT-6160 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader of VAV1, which in preclinical studies has shown deep degradation of its target with no detectable effects on other proteins. VAV1 is a key signaling protein downstream of both the T- and B-cell receptors. VAV1 expression is restricted to immune cells, including T and B cells. MRT-6160 has shown promising activity in preclinical models of multiple immune-mediated conditions. In a Phase 1, single ascending dose / multiple

ascending dose (SAD/MAD) study in healthy subjects (clinicaltrials.gov identifier NCT06597799), MRT-6160 demonstrated sustained, dose-dependent VAV1 degradation in peripheral blood T and B cells after single and multiple dose administration. MRT-6160 also substantially inhibited secretion of inflammatory cytokines from whole blood derived T and B cells following *ex vivo* stimulation. Under the terms of an agreement announced in October 2024, Novartis has exclusive worldwide rights to develop, manufacture and commercialize MRT-6160 and other VAV1 MGDs. Monte Rosa is eligible to receive up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies. Monte Rosa will co-fund any Phase 3 clinical development and will share 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.

About MRT-8102
MRT-8102 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader (MGD) that targets NEK7 for the treatment of inflammatory diseases linked to NLRP3, IL-1β, and IL-6 dysregulation. NEK7 has been shown to be required for NLRP3 inflammasome assembly, activation and IL-1β release both *in vitro* and *in vivo*. Aberrant NLRP3 inflammasome activation and the subsequent release of active IL-1β and interleukin-18 (IL-18) has been implicated in multiple inflammatory disorders, including cardiovascular disease, gout, osteoarthritis, neurologic disorders including Parkinson's disease and Alzheimer's disease, and metabolic disorders. In a non-human primate model, MRT-8102 was shown to potently, selectively, and durably degrade NEK7, and resulted in near-complete reductions of IL-1β and caspase-1 following *ex vivo* stimulation of whole blood. MRT-8102 has demonstrated a considerable safety margin (>200-fold exposure margin over projected human efficacious dose) in GLP toxicology studies.

About MRT-2359
MRT-2359 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader (MGD) of GSPT1. MYC transcription factors (c-MYC, L-MYC and N-MYC) are well-established drivers of human cancers that maintain high levels of protein translation, which is critical for uncontrolled cell proliferation and tumor growth. Preclinical studies have shown this addiction to MYC-induced protein translation creates a dependency on GSPT1. By inducing degradation of GSPT1, MRT-2359 is designed to exploit this vulnerability, disrupting the protein synthesis machinery, leading to anti-tumor activity in MYC-driven tumors. MRT-2359 is being investigated in an ongoing Phase 1/2 study (clinicaltrials.gov identifier NCT05546268) in solid tumors, including castration-resistant prostate cancer (CRPC). In heavily pretreated CRPC patients, a patient group characterized by widespread expression of c-MYC, MRT-2359 demonstrated encouraging early signals of clinical response.

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 in the areas of oncology, autoimmune and inflammatory diseases, and more. 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 MGDs, which spans autoimmune and inflammatory diseases, oncology, and beyond. Monte Rosa has a global license agreement with Novartis to advance VAV1-directed molecular glue degraders and a strategic collaboration

with Roche to discover and develop MGDs against targets in cancer and neurological diseases previously considered impossible to drug. 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, unlocking new opportunities to address previously undruggable therapeutic targets, 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, (ii) the ongoing development and progress of our NEK7-directed MGD, referred to as MRT-8102, including our expectations regarding initial data in the first half of 2026 and statements regarding our beliefs that MRT-8102 offers a differentiated, oral approach to potentially address a range of inflammatory and cardio-immunology indications, (iii) the ongoing development of a second-generation NEK7-directed MGD optimized for CNS penetration and our statements around expected IND submission in 2026, (iv) our ongoing clinical development of MRT-2359, statements relating our ability to continue and expand the enrollment of patients with CRPC and HR+ breast cancer and statements regarding the timing for data readouts in the second half of 2025 and (v) statements around the progress of both our CDK2 and cyclin E1-directed MGD programs, including statements around the nomination of a development candidate in the second half of 2025 and timing of submission of an IND application in 2026, 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 the ability to optimize collaborations with industry partners on our development programs, statements about obligations under our collaboration agreements, expectations around the receipt of any payments under such agreements and the future 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, ability to fund operations into 2028, 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, 2024, filed with the U.S. Securities and Exchange Commission on March 20, 2025, 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)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 69,429	$ 224,254
Marketable securities	221,165	147,895
Other receivables	2,370	173
Prepaid expenses and other current assets	6,501	5,118
Total current assets	299,465	377,440
Property and equipment, net	29,052	29,483
Operating lease right-of-use assets	25,674	26,831
Restricted cash	4,950	4,863
Other long-term assets	445	115
Total assets	$ 359,586	$ 438,732
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,581	$ 17,215
Accrued expenses and other current liabilities	13,767	18,785
Current deferred revenue	18,410	117,232
Current portion of operating lease liability	4,094	3,714
Total current liabilities	41,852	156,946
Deferred revenue, net of current	8,059	16,147
Defined benefit plan liability	4,558	3,702
Operating lease liability, net of current	37,037	39,001
Total liabilities	91,506	215,796
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 61,717,349 and 61,507,446 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	6	6
Additional paid-in capital	675,445	664,874
Accumulated other comprehensive loss	(3,373)	(3,356)
Accumulated deficit	(403,998)	(438,588)
Total stockholders' equity	268,080	222,936
Total liabilities and stockholders' equity	$ 359,586	$ 438,732

Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 23,194	$ 4,695	$ 108,123	$ 5,759
Operating expenses:				
Research and development	30,653	28,055	62,843	55,081
General and administrative	8,095	9,282	16,798	18,267
Total operating expenses	38,748	37,337	79,641	73,348
(Loss) income from operations	(15,554)	(32,642)	28,482	(67,589)
Other income:				
Interest income	3,068	2,637	6,507	5,079
Foreign currency exchange gain (loss), net	1,390	(53)	1,563	567
Gain on disposal of property and equipment	—	—	59	—
Total other income	4,458	2,584	8,129	5,646
Net (loss) income before income taxes	$ (11,096)	$ (30,058)	$ 36,611	$ (61,943)
Provision for income taxes	(1,199)	(252)	(2,021)	(335)
Net (loss) income	$ (12,295)	$ (30,310)	$ 34,590	$ (62,278)

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