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): September 8, 2026

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 7.01. Regulation FD Disclosure

On September 8, 2026, Monte Rosa Therapeutics, Inc. (the "Company") issued a press release announcing the achievement of a milestone associated with the initiation of a Phase 2 clinical study for the VAV1-directed molecular glue degrader ("MGD") MRT-6160 (DDY391) in participants with Sjögren's disease. The study is being conducted by the Company's collaborator, Novartis AG ("Novartis"). 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 in Item 7.01 of this 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 8.01. Other Events

As previously disclosed, the Company is party to a global exclusive development and commercialization license agreement (the "Novartis Agreement") with Novartis pursuant to which Novartis has exclusive worldwide rights to develop, manufacture and commercialize VAV1-directed MGDs, including MRT-6160 (DDY391). Under the terms of the Novartis Agreement, the Company is eligible to receive up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies. Pursuant to the terms of the Novartis Agreement, the initiation of the Phase 2 clinical study in the first indication triggered a $50 million milestone payment from Novartis to the Company.

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 the receipt of milestone and other payments under the Novartis Agreement and the future development and commercialization of VAV1-directed MGDs, including MRT-6160 (DDY391), 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, most recent Quarterly Reports on Form 10-Q 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, as well as the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials. 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Press Release issued by Monte Rosa Therapeutics, Inc. dated September 8, 2026.
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: September 8, 2026

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

Exhibit 99.1

Monte Rosa Therapeutics Announces Milestone Achievement Associated with Initiation of Phase 2 Clinical Study for VAV1-directed Molecular Glue Degrader MRT-6160 (DDY391)

Phase 2 study to be conducted in participants with Sjögren's disease

Novartis conducting study under global exclusive development and commercialization license agreement with Monte Rosa

Monte Rosa to receive milestone payment based on first patient visit of Phase 2 clinical study

Additional studies expected to evaluate the potential of MRT-6160 (DDY391) across immune-mediated diseases; Monte Rosa eligible for additional Phase 2 study initiation milestones

BOSTON, Mass., September 8, 2026 – Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced that its collaborator Novartis has initiated a Phase 2 clinical study for the VAV1-directed MGD MRT-6160 (DDY391) in people living with Sjögren's disease (SjD), the second most prevalent rheumatic autoimmune disease[1]. This study is the first of several studies expected for MRT-6160 (DDY391) and part of a global exclusive development and commercialization license agreement between Monte Rosa and Novartis to advance VAV1 MGDs including MRT-6160 (DDY391). In connection with the first patient visit of the study, Monte Rosa will receive a $50 million milestone payment from Novartis.

"We are very pleased that Novartis is advancing MRT-6160 into clinical development for Sjögren's disease by launching a global Phase 2 study," said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. "Sjögren's disease is not only an area of high unmet medical need, but also an indication driven by both pathogenic autoimmune T cells and B cells and so well-aligned with the biological effects of a VAV1-directed MGD. We believe this milestone reflects the strong progress being made in the program, and further validates the potential of our QuEEN™ product engine to address disease-driving proteins that have long been considered undruggable. We look forward to the continued development of MRT-6160, and to building on the momentum across our partnered and wholly owned pipeline as we work to bring meaningful new therapeutic options to patients."

This study is a Phase 2a/b, randomized, double-blind, placebo-controlled, multi-center trial to evaluate efficacy, safety, and tolerability of up to 52 weeks of treatment with MRT-6160 (DDY391) in participants with Sjögren's disease, to support dose selection for Phase 3. More information about the study, "A Phase 2a/b Study to Assess the Efficacy, Safety and Tolerability of DDY391 in Participants With Sjögren's Disease," can be found at ClinicalTrials.gov, study identifier: NCT07737743.

MRT-6160 (DDY391) is a potent, highly selective, and orally bioavailable investigational molecular glue degrader of VAV1, a key signaling protein downstream of both the T- and B-cell receptors. Available preclinical and clinical data support the potential of MRT-6160 (DDY391) to address multiple immune-mediated diseases. In a Phase 1 study, MRT-6160 (DDY391) demonstrated sustained, dose-dependent VAV1

degradation of greater than 90% in peripheral blood T cells after single and multiple-dose administration, as well as suppression of key inflammatory biomarkers. The administration of MRT-6160 (DDY391) was generally well tolerated, with no serious adverse effects observed.

About Sjögren's Disease
Sjögren's disease is a serious, progressive, autoimmune disease that affects approximately 0.25% of the population[2] and impacts multiple organs, causing a wide spectrum of symptoms such as dryness, fatigue, pain, and an increased risk of lymphoma, which can carry a significant burden and impact on quality of life[3,4]. Its heterogeneous nature often causes it to go unrecognized or misdiagnosed[5]. It is estimated that 50% of people with Sjögren's disease are undiagnosed[6].

Novartis Agreement Details
Monte Rosa has a global exclusive development and commercialization license agreement with Novartis to advance VAV1-directed MGDs, including MRT-6160. Under the terms of the agreement, Novartis has exclusive worldwide rights to develop, manufacture and commercialize MRT-6160 and other VAV1 MGDs and is responsible for all clinical development and commercialization, starting with Phase 2 clinical studies. 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.

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.

References

1. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Committee on Selected Immune Disorders and Disability. Sjögren's Disease/Syndrome. [Last accessed: December 2025] https://www.ncbi.nlm.nih.gov/books/NBK584486/
2. Conrad N, et al. Incidence, prevalence, and co-occurrence of autoimmune disorders over time and by age, sex, and socioeconomic status: a population-based cohort study of 22 million individuals in the UK. Lancet. 2023;401(10391):1878–1890
3. Negrini S, et al. Sjögren's syndrome: a systemic autoimmune disease. Clin Exp Med. 2022; 22(1):9–25
4. Mariette X, Criswell LA. Primary Sjögren's symptoms. N Engl J Med. 2018;378:931–939

5. Gairy K, et al. Burden of illness among subgroups of patients with primary Sjögren's syndrome and systemic involvement. Rheumatology. 2021; 60(4):1871–188
6. Narváez J, et al. Prevalence of Sjögren's syndrome in the general adult population in Spain: estimating the proportion of undiagnosed cases. Sci Rep. 2020;10(1):10627

Forward-Looking Statements

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