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 15, 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 1.01. Entry into a Material Definitive Agreement

On September 13, 2025, Monte Rosa Therapeutics AG ("Monte Rosa AG," hereinafter the "Company"), a wholly-owned subsidiary of Monte Rosa Therapeutics, Inc., and Novartis Pharma AG ("Novartis") entered into a Collaboration, Option, and License Agreement (the "Agreement") to discover and develop degraders to treat immune-mediated diseases using the Company's QuEEN™ product engine. Pursuant to the Agreement, the Company has granted Novartis an exclusive, royalty-bearing, sublicensable and transferable license to degraders for one immunology and inflammation ("I&I") program (the "First Licensed Program") and the exclusive option to obtain exclusive, royalty-bearing, sublicensable and transferable licenses with respect to two programs from the Company's growing preclinical immunology portfolio (the "Options" and the programs, the "Optioned I&I Programs"). Such Options are individually exercisable at Novartis' discretion until a program meets criteria for investigational new drug application-filing-readiness. On a program-by-program basis, if Novartis does not exercise an Option, all rights with respect to such program are retained by the Company; if Novartis does exercise its Option, such program becomes a Licensed Program (together, with the First Licensed Program, the "Licensed Programs"). Under the Agreement, the Company will apply its proprietary AI/ML-enabled QuEEN™ product engine for the discovery and development of degraders for the First Licensed Program and the Optioned I&I Programs. The Licensed Programs will be further developed and commercialized by Novartis, unless otherwise agreed to by the parties in accordance with the Agreement. Research activities for the Licensed Programs governed by the Agreement will be overseen by a Joint Research Committee.

Pursuant to the Agreement, the Company is entitled to receive from Novartis (1) an upfront payment of $120.0 million and (2) payments to maintain the Options totaling up to $60.0 million, and is eligible to receive from Novartis (1) preclinical milestone payments relating to the First Licensed Program and option exercise payments related to the Options of up to $180.0 million, (2) up to $5.4 billion in clinical development, regulatory, and sales milestones relating to the First Licensed Program and the two Optioned I&I Programs, beginning upon initiation of Phase 1 studies, including (a) potential development and regulatory milestone payments up to $2.2 billion if regulatory approval is achieved for multiple indications in multiple territories and (b) potential sales milestones payments up to $3.2 billion, allocated across licensed products, and (3) tiered royalties on global net sales in the high-single to low double-digit range for the First Licensed Program and in the low double-digit range for the two Optioned I&I Programs. The Company will be responsible for costs related to research activities, while Novartis will be responsible for costs related to development and commercialization activities.

The Agreement includes customary termination provisions, including Novartis' ability to terminate the Agreement in its entirety.

The foregoing description is qualified in its entirety by reference to the complete text of the Agreement, which the Company plans to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2025, with confidential portions redacted.

Item 7.01. Regulation FD Disclosure

On September 15, 2025, the Company issued a press release announcing entry into the Collaboration, Option, and License Agreement. A copy of the press release is furnished hereto as Exhibit 99.1.

On September 15, 2025, the Company posted a revised presentation to the "Presentations" section of the Company's website at https://www.monterosatx.com/.

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.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" of the Company within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding expectations regarding the closing of the transaction with Novartis, the receipt of upfront, milestone and other payments under the Agreement, the payments and activities associated with the First Licensed Program and the Options, and the future development and commercialization of the degraders. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in the Company's other and subsequent filings with the Securities and Exchange Commission. All information in this Current Report on Form 8-K is as of the date of this Current Report on Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Press Release issued by Monte Rosa Therapeutics, Inc. dated September 15, 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: September 15, 2025

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

Monte Rosa Therapeutics Announces Collaboration with Novartis for Degraders to Treat Immune-mediated Diseases

Novartis receives an exclusive license to an undisclosed discovery target

Novartis also receives options to license two programs from Monte Rosa's growing preclinical immunology portfolio

Monte Rosa to receive an upfront payment of $120 million, plus option maintenance payments, and is eligible for option exercise payments and development, regulatory, and sales milestones, as well as tiered royalties on global net sales

Extended cash runway enables Monte Rosa to accelerate preclinical and clinical-stage immunology & inflammation (I&I) pipeline

BOSTON, Mass., September 15, 2025 – Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced an agreement to collaborate with Novartis to develop novel degraders for immune- mediated diseases. The agreement is the Company's second with Novartis, in addition to the global exclusive license agreement for Monte Rosa's VAV1 degraders including MRT-6160, announced in October 2024.

The agreement announced today was uniquely structured by the companies to collaborate on accelerating development of degraders for important immune-mediated diseases driven by highly credentialed and difficult-to-drug targets. Under the agreement, Monte Rosa's scientists will apply their proprietary AI/ML-enabled QuEEN™ product engine for the discovery and development of degraders to be further developed and commercialized by Novartis.

"We are extremely excited to extend our relationship with Novartis beyond our previously announced VAV1 agreement given the strong progress made to advance MRT-6160 toward initiation of multiple Phase 2 studies in immune-mediated diseases," said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. "We believe this new agreement further strengthens our relationship with Novartis, a recognized global leader in immune-mediated diseases, and reflects the expansive opportunity in the space for our highly selective and potent MGDs. Our AI/ML-enabled QuEEN™ product engine continues to generate new insights and opportunities, delivering an expanding pipeline of programs directed against a breadth of historically undruggable immunology targets. This new collaboration allows us to expedite the development of certain of those programs with Novartis, leveraging their recognized development and commercialization capabilities. The agreement further strengthens our financial position, which allows us to progress our wholly owned programs, including multiple undisclosed targets in Th1, Th2, and Th17-driven autoimmune conditions, and provides runway beyond multiple anticipated Phase 2 readouts for MRT-8102, MRT-6160, and MRT-2359."

"We are pleased to expand our collaboration with Monte Rosa Therapeutics, building on the strong foundation and progress established through the VAV1 program," said Fiona Marshall, Ph.D., President of Biomedical Research at Novartis. "This new agreement underscores our commitment to advancing targeted protein degradation as a promising approach to address immune-mediated diseases with high unmet need. We believe Monte Rosa's QuEEN™ platform has the potential to uncover new insights in this field. We look forward to working together to translate these insights into transformative therapies for patients."

Agreement Details and Financial Terms

Under the terms of the agreement, Monte Rosa will receive an upfront payment of $120 million. Monte Rosa will also receive payments to maintain the options. In total deal value, Monte Rosa is eligible to receive up to $5.7 billion, including upfront, option maintenance, preclinical milestone, option exercise, and development, regulatory, and sales milestone payments across programs, as well as tiered royalties on global net sales in the high single to low double-digit range.

Monte Rosa's publicly disclosed pipeline programs are outside the scope of this agreement.

Monte Rosa plans to provide further information regarding its updated cash position and runway in its third quarter 2025 earnings update.

Lazard served as the exclusive financial advisor to Monte Rosa for this agreement.

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. 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 obligations under the Collaboraton Agreement, the receipt of upfront, option maintenance payments, option exercise payment and development, regulatory, and sales milestone payments, as well as tiered royalties on global net sales under the agreement, the Company's growing preclinical immunology portfolio, the development progress and future commercialization of VAV1 MGDs, including MRT-6160, our expectations regarding the expansive opportunity in the space for our highly selective and potent MGDs, our belief that our AI/ML-enabled QuEEN™ product engine will continue to generate new insights and opportunities, delivering an expanding pipeline of programs directed against a breadth of historically undruggable immunology targets, statements relating to our relationship with Novartis, our expectation that this collaboration will allow us to expedite the development of certain of our programs, statements around the advancement and application of our pipeline, and the planned update related to our financial position and cash runway, 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.

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