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): October 25, 2024

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 October 25, 2024, 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 License Agreement (the "Agreement"). Pursuant to the Agreement, the Company will grant to Novartis an exclusive, royalty-bearing, sublicensable and transferable license to develop, manufacture, and commercialize VAV1 molecular glue degraders ("MGDs"), including MRT-6160, which is currently in Phase 1 clinical development for immune-mediated conditions. The Company is responsible for completing the ongoing Phase 1 clinical study and Novartis is responsible for all subsequent development and commercial activities starting at Phase 2. Development and commercial activities governed by the Agreement will be overseen by a Development Committee and a Commercialization Committee.

Pursuant to the Agreement, the Company is entitled to receive from Novartis (1) an upfront payment of $150 million, (2) up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies including (a) potential development and regulatory milestone payments, exceeding $1.5 billion if multiple indications achieve regulatory approval in multiple territories, (b) potential sales milestones payments in connection with sales outside of the United States, and (3) tiered royalties on sales outside of the United States. The Company will continue to be responsible for costs associated with the ongoing Phase 1 clinical study and Novartis will be responsible for costs associated with any subsequent clinical studies. The Company and Novartis also agreed to a net profit and loss sharing arrangement, pursuant to which the Company will co-fund any global clinical development from Phase 3 onwards and will share 30% of any profits and losses associated with the manufacturing and commercialization of the licensed products in the United States. The Company has defined opportunities to opt out of the net profit and loss sharing arrangement, in such case, sales in the United States would be entitled to the potential sales milestones payments and tiered royalties on sales available outside of the United States. Any costs for any co-funded development and commercialization activities are subject to budgets reviewed by the Development Committee and Commercialization Committee, respectively.

The Agreement is subject to customary closing conditions, including regulatory clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

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

Item 7.01. Regulation FD Disclosure

On October 28, 2024, the Company issued a press release announcing its entry into the Agreement. A copy of the press release is furnished hereto as Exhibit 99.1.

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 future development and commercialization of VAV1 MGDs, including MRT-6160. 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 October 28, 2024.
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: October 28, 2024

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

Monte Rosa Therapeutics Announces Global License Agreement with Novartis to Advance T and B Cell-modulating VAV1-directed Molecular Glue Degraders

Agreement expected to accelerate MRT-6160 clinical development and broadly explore therapeutic opportunities across multiple indications

Monte Rosa to receive up-front payment of $150 million and is eligible to receive milestone payments, U.S. profit and loss share, and tiered royalties on ex-U.S. net sales

BOSTON, Mass., October 28, 2024 – Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced a global exclusive development and commercialization license agreement with Novartis to advance VAV1 MGDs, including MRT-6160. MRT-6160 is currently in an ongoing Phase 1, single ascending dose (SAD)/multiple ascending dose (MAD) healthy volunteer study for immune-mediated conditions. Under the terms of the agreement, Novartis will obtain exclusive worldwide rights to develop, manufacture and commercialize MRT-6160 and other VAV1 MGDs and will be responsible for all clinical development and commercialization, starting with Phase 2 clinical studies. Monte Rosa remains responsible for completion of the ongoing Phase 1 clinical study of MRT-6160.

“We are thrilled to announce this agreement with Novartis, a key player in immune-mediated conditions, and we are excited about the transformative potential it provides for Monte Rosa and MRT-6160. We expect this will accelerate and broaden the scope of clinical development of MRT-6160 to advance this unique, orally bioavailable modality while retaining substantial value for Monte Rosa. We believe the transaction validates our unique and industry leading QuEEN™ discovery engine, and it further increases our conviction to rationally design and develop highly selective and safe MGDs for undruggable targets, including in the areas of immunology and inflammation, metabolism, and genetic diseases,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “The financial resources provided by this agreement are expected to extend our operational runway, enable us to advance our pipeline to potential value-creating milestones and anticipated proof-of-concept readouts, and further leverage our QuEEN™ discovery engine.”

"Novartis has had a long-standing interest in molecular glue degraders, which offer the potential to tackle challenging biological targets. We are excited about their application in immunology and the early progress we have seen by Monte Rosa in this space and with MRT-6160. We look forward to advancing MRT-6160 and learning more about its potential to provide a new therapeutic option for people living with a range of immune-mediated conditions,” said Fiona Marshall, President of Biomedical Research at Novartis. “Novartis is committed to bringing forward new therapeutic options for these patients, and we are happy to be working with Monte Rosa to harness the potential of this approach to address unmet medical needs.”

MRT-6160 is a potent, highly selective, and orally bioavailable investigational degrader of VAV1, a key signaling protein downstream of both the T- and B-cell receptors. Preclinical studies have demonstrated deep degradation of VAV1, resulting in a significant decrease in cytokines linked to immune-mediated conditions, with no detectable effects on other proteins. MRT-6160 has shown promising activity in preclinical models of multiple immune-mediated conditions.

Agreement Details and Financial Terms
Under the terms of the agreement, Novartis has agreed to pay Monte Rosa $150 million up front. Monte Rosa is eligible to receive up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies, as well as tiered royalties on ex-U.S. net sales. 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.

The agreement is subject to customary closing conditions including regulatory clearance.

Monte Rosa plans to provide further information regarding its updated cash position and runway in its third quarter 2024 earnings update.

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 identify degradable protein targets and rationally design MGDs with unprecedented selectivity. The QuEEN discovery engine enables access to a wide-ranging and differentiated target space of well-validated biology across multiple therapeutic areas. Monte Rosa has developed the industry's leading pipeline of MGDs, which spans oncology, autoimmune and inflammatory disease and beyond, and has 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 the closing of the transaction with Novartis, obligations under the Agreement, the receipt of upfront, milestone and other payments under the Agreement, the future development and commercialization of VAV1 MGDs, including MRT-6160, our VAV1-directed degrader, referred to as MRT-6160, our expectations regarding the potential clinical scope and benefit for this program, including results of preclinical studies, and our expectations of timings for the program, statements around the advancement and application of our pipeline, and the planned update related to 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, 2023, filed with the U.S. Securities and Exchange Commission on March 14, 2024, 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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