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 10, 2023

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 10, 2023, Monte Rosa Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2023. 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 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 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Press Release issued by Monte Rosa Therapeutics, Inc. dated August 10, 2023.
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 10, 2023

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

Monte Rosa Therapeutics Announces Second Quarter 2023 Financial Results and Provides Corporate Update

- On track to present initial data from Phase 1/2 clinical trial of MRT-2359 for MYC-driven solid tumors in the second half of 2023
- Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for MRT-2359 for the treatment of small cell lung cancer (SCLC)
- Announced development candidate MRT-6160, a novel, highly selective molecular glue degrader of VAV1, with IND submission expected 1H 2024
- Strong cash position expected to sustain operations into 2025 and enable advancement of pipeline of novel molecular glue degraders

BOSTON, Mass., August 10, 2023 – 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 quarter ended June 30, 2023.

"During the second quarter, we continued focusing on advancing our clinical and preclinical portfolios, marking significant milestones, including the nomination of MRT-6160 as the development candidate for our VAV1 program. MRT-6160 is a potent, highly selective and orally bioavailable VAV1-targeting MGD. By selectively degrading VAV1, a protein pivotal to T and B cell signaling, MRT-6160 is designed to help patients with a range of severe autoimmune conditions. We expect to file an IND application for MRT-6160 in the first half of 2024," said Markus Warmuth, M.D., CEO of Monte Rosa Therapeutics. "Moreover, the Phase 1/2 trial of MRT-2359, our GSPT1-directed MGD, in MYC-driven solid tumors is enrolling well and we anticipate sharing initial clinical data this year. Our strong cash reserve supports further development of our groundbreaking pipeline of investigational MGD-based medicines and the discovery of additional MGD development candidates through our innovative QuEEN™ discovery engine."

In addition, this morning, Monte Rosa announced the resignation of Ajim Tamboli, CFA, who has served as the Company's Chief Financial Officer (CFO). "Ajim was an instrumental part of Monte Rosa's path to and through its initial public offering (IPO) and of the Company's leadership team. We thank him for his service to the Company and wish him all the best in his future endeavors," said Dr. Warmuth.

SECOND QUARTER 2023 AND RECENT HIGHLIGHTS

- Announced development candidate MRT-6160, a VAV1-directed MGD, for the treatment of autoimmune diseases
- Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for MRT-2359 for the treatment of small cell lung cancer (SCLC)
- Presented preclinical data highlighting the preferential activity of MRT-2359, an orally bioavailable GSPT1-directed MGD, in MYC-driven solid tumors at the 2023 American Association for Cancer Research (AACR) Annual Meeting

UPCOMING MILESTONES

- On track to present initial Phase 1/2 clinical data for MRT-2359 in MYC-driven solid tumors, including pharmacokinetics (PK), pharmacodynamics (PD), safety, and available initial efficacy data, in the second half of 2023
- On track for planned IND submission for MRT-6160 in the first half of 2024

- On track to nominate development candidates for one or more additional preclinical programs in the second half of 2023

SECOND QUARTER 2023 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for the second quarter of 2023 were $29.1 million, compared to $20.9 million for the second quarter of 2022. These increases were driven by the successful achievement of key milestones in our R&D organization, including the advancement of MRT-2359 in the clinic, the progression of our preclinical pipeline, and the continued development of the Company's QuEEN™ platform for discovery efforts. The increase in R&D expenses was driven by increased headcount and laboratory-related expenses to achieve these milestones. Non-cash stock-based compensation constituted $2.3 million of R&D expenses for Q2 2023, compared to $1.4 million in the same period in 2022.

General and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2023 were $8.1 million compared to $6.3 million for the second quarter of 2022. The increase in G&A expenses was a result of increased headcount and expenses in support of the company's growth and operations. G&A expenses included non-cash stock-based compensation of $1.9 million for the second quarter of 2023, compared to $1.4 million for the same period in 2022.

Net Loss: Net loss for the second quarter of 2023 was $35.2 million, compared to $26.5 million for the second quarter of 2022.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of June 30, 2023, were $207.6 million, compared to cash, cash equivalents, restricted cash, and marketable securities of $237.0 million as of March 31, 2023. The decrease of $29.4 million was primarily related to cash used to fund operations. The company expects its cash and cash equivalents will be sufficient to fund planned operations and capital expenditures into 2025.

About MRT-2359
MRT-2359 is a potent, selective and orally bioavailable investigational molecular glue degrader (MGD) that induces the interaction between the E3 ubiquitin ligase component cereblon and the translation termination factor GSPT1, leading to the targeted degradation of GSPT1 protein. The 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.

About MRT-6160
MRT-6160 is a potent, highly selective, and orally bioavailable investigational degrader of VAV1, which in our *in vitro* studies has shown deep degradation of its target with no detectable effects on other proteins. VAV1, a Rho-family guanine nucleotide exchange factor, is a key signaling protein downstream of both the T-and B-cell receptors. VAV1 expression is restricted to blood and immune cells, including T and B cells. Preclinical studies have shown that targeted degradation of VAV1 protein via an MGD modulates both T-

and B-cell receptor-mediated activity. This modulation is evident both *in vitro* and *in vivo*, demonstrated by a significant decrease in cytokine secretion, proteins vital for maintaining autoimmune diseases. Moreover, VAV1-directed MGDs have shown promising activity in preclinical models of autoimmune diseases and thus have the potential to provide therapeutic benefits in multiple autoimmune indications, such as multiple sclerosis, rheumatoid arthritis, and dermatological disorders. Preclinical studies demonstrate MRT-6160 inhibits disease progression in *in vivo* autoimmunity models.

About Monte Rosa

Monte Rosa Therapeutics is a biotechnology company developing novel molecular glue degrader (MGD) medicines for patients living with serious diseases such as oncology, autoimmune and inflammatory diseases. The Company's lead program, MRT-2359, is being developed in a Phase 1/2 study in MYC-driven tumors, including non-small cell lung cancer and small-cell lung cancer. MGDs are small molecule protein degraders designed to employ the body's natural mechanisms to eliminate therapeutically relevant proteins selectively. The Company's QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) platform enables it to rapidly identify protein targets and design highly selective degraders by combining diverse libraries of proprietary MGDs with in-house proteomics, structural biology, A.I./machine learning, and computational chemistry capabilities. 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 product development activities, our ongoing clinical development of our GSPT1 degrader referred to as MRT-2359, including our expectations for the nature, significance, and timing for our disclosure of any initial data from our Phase 1/2 clinical trial of MRT-2359 in MYC-driven solid tumors, statements about the advancement of our preclinical programs, pipeline and the various products therein, including the ongoing development of our VAV1-directed degrader, referred to as MRT-6160, and the planned submission of an IND to the FDA for MRT-6160 in the first half of 2024, our expectations regarding the potential clinical benefit for this program and our expectations of timings for the program, statements around the advancement and application of our pipeline and platform, and statements concerning our expectations regarding our ability to nominate and the timing of our nominations of additional targets, product candidates, and development candidates, as well as our expectations of success for our programs 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, 2023, filed with the U.S. Securities and Exchange Commission on March 16, 2023, 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.

Consolidated Balance Sheets
(in thousands, except share amounts)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 47,027	$ 54,912
Marketable securities	156,039	207,914
Other receivables	1,154	7,656
Prepaid expenses and other current assets	3,884	4,444
Current restricted cash	—	960
Total current assets	208,104	275,886
Property and equipment, net	35,335	27,075
Operating lease right-of-use assets	30,359	34,832
Restricted cash, net of current	4,527	4,318
Other long-term assets	291	278
Total assets	$ 278,616	$ 342,389
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,308	$ 7,862
Accrued expenses and other current liabilities	11,114	14,580
Current portion of operating lease liability	2,667	3,127
Total current liabilities	19,089	25,569
Defined benefit plan liability	1,505	1,533
Operating lease liability	44,368	43,874
Total liabilities	64,962	70,976
Commitments and contingencies		
Stockholders' equity		
Common stock	5	5
Additional paid-in capital	513,041	503,696
Accumulated other comprehensive loss	(1,640)	(1,752)
Accumulated deficit	(297,752)	(230,536)
Total stockholders' equity	213,654	271,413
Total liabilities and stockholders' equity	$ 278,616	$ 342,389

Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 29,076	$ 20,936	$ 55,831	$ 38,851
General and administrative	8,145	6,295	15,649	12,682
Total operating expenses	37,221	27,231	71,480	51,533
Loss from operations	(37,221)	(27,231)	(71,480)	(51,533)
Other income:				
Interest income, net	2,302	628	4,739	777
Foreign currency exchange gain (loss), net	(93)	134	(178)	230
Gain on disposal of fixed assets	24	—	24	125
Loss on sale of marketable securities	—	—	(131)	—
Total other income	2,233	762	4,454	1,132
Net loss before income taxes	(34,988)	(26,469)	(67,026)	(50,401)
Provision for income taxes	(190)	—	(190)	—
Net loss	$ (35,178)	$ (26,469)	$ (67,216)	$ (50,401)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.71)	$ (0.57)	$ (1.36)	$ (1.08)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	49,431,922	46,668,369	49,389,931	46,632,279
Net loss	$ (35,178)	$ (26,469)	$ (67,216)	$ (50,401)
Other comprehensive income (loss):				
Provision for pension benefit obligation	14	33	28	67
Unrealized gain (loss) on available-for-sale securities	(261)	(358)	84	(504)
Comprehensive loss	$ (35,425)	$ (26,794)	$ (67,104)	$ (50,838)

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