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): November 9, 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 November 9, 2023, Monte Rosa Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 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 November 9, 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: November 9, 2023

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

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

Interim data from Phase 1/2 clinical trial of MRT-2359 demonstrated tumor reductions in patients with biomarker-positive cancers; recommended Phase 2 dose expected in Q2 2024

Announced strategic collaboration with Roche to discover novel molecular glue degraders targeting cancer and neurological diseases; $50 million upfront payment

Presented preclinical data demonstrating that MRT-6160, a VAV1-targeting MGD, attenuates autoimmune disease progression; IND submission expected 1H 2024

Completed $25 million registered direct offering from a life sciences-dedicated investor

Strong cash position expected to fund operations into H1 2026 and enable advancement of GSPT1, VAV1 and NEK7 pipeline programs through clinical milestones

BOSTON, Mass., November 9, 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 September 30, 2023.

"This has been a pivotal time for Monte Rosa as we announced both our first clinical data and our first major strategic collaboration," said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. "We're very excited about the clinical data for MRT-2359, our GSPT1-directed molecular glue degrader, and in particular the early signs of clinical activity in MYC-driven solid tumors. We're equally excited to partner with Roche to enable and accelerate expansion of our QuEEN™ discovery engine to discover and develop molecular glues against targets previously considered impossible to drug for cancer and neurological diseases. We also completed a registered direct offering that, together with our ongoing pipeline prioritization efforts, is expected to extend our cash runway into the first half of 2026. We look forward to continuing to execute on our pipeline, including delivering Phase 2 interim data for MRT-2359 and Phase I healthy volunteer data for our immunology and inflammation-directed VAV1 and NEK7 programs."

THIRD QUARTER 2023 AND RECENT HIGHLIGHTS

- Announced interim clinical data from the ongoing MRT-2359 Phase 1/2 study demonstrating favorable pharmacokinetic (PK), pharmacodynamic (PD), and tolerability profiles in heavily pre-treated patients with MYC-driven solid tumors, including lung cancers and high-grade neuroendocrine tumors. MRT-2359 showed evidence of tumor size reductions, including partial responses, in heavily pretreated patients with biomarker-positive tumors. Optimal PD modulation of GSPT1 in peripheral blood mononuclear cells and tumor tissue biopsies was observed at all dose levels, consistent with its designed activity based on preclinical studies.
- Entered into a strategic collaboration and licensing agreement with global healthcare leader Roche to discover and develop MGDs against targets in cancer and neurological diseases. Under the terms of the agreement, Monte Rosa Therapeutics will receive an upfront payment of $50 million, and is eligible to receive future preclinical, clinical, commercial and sales milestone payments that could exceed $2 billion, as well as tiered royalties.

- Completed a $25 million registered direct offering, priced at-the-market under Nasdaq rules, with a life sciences-dedicated investor.
- Presented preclinical data at the American College of Rheumatology (ACR) Convergence Annual Meeting demonstrating the potential of MRT-6160, a VAV1-targeting MGD, to treat immunological and inflammatory diseases. The data show that MRT-6160 attenuated disease progression in a murine collagen-induced arthritis (CIA) model.
- Appointed Anthony M. Manning, Ph.D., to the Company's Board of Directors. Dr. Manning is a highly accomplished drug discovery leader in the field of autoimmune and inflammatory diseases.
- Discontinued sickle cell disease program to prioritize internal efforts on ongoing clinical-, Investigational New Drug (IND)- and lead optimization-stage programs.

UPCOMING MILESTONES

- The Company now expects to release the recommended Phase 2 dose for the MRT-2359 Phase 1/2 study in Q2 2024.
- On track for planned IND submission for MRT-6160 in the first half of 2024.
- The Company expects to nominate a development candidate for its NEK7 preclinical program in Q1 2024.
- The Company expects to nominate a development candidate for its CDK2 preclinical program in 2024.

THIRD QUARTER 2023 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2023 were $28.3 million, compared to $21.3 million for the third 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 Q3 2023, compared to $1.7 million in the same period in 2022.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2023 were $8.7 million compared to $7.0 million for the third 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 $2.2 million for the third quarter of 2023, compared to $1.5 million for the same period in 2022.

Net Loss: Net loss for the third quarter of 2023 was $34.9 million, compared to $27.3 million for the third quarter of 2022.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2023, were $183.0 million, compared to cash, cash equivalents, restricted cash, and marketable securities of $207.6 million as of June 30, 2023. The decrease of $24.6 million was primarily related to cash used to fund operations. The September 30, 2023, cash and equivalents balance does not include the $50 million upfront payment from Roche or the approximately $25 million proceeds from the registered direct offering, which were received after the end of Q3 2023.

The company expects its cash and cash equivalents, including proceeds from the Roche collaboration, will be sufficient to fund planned operations and capital expenditures into the first half of 2026.

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 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. Monta 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 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, timing for our identification and any disclosure of a recommended phase 2 dose for MRT-2359, 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, including identification and the timing thereof of a development candidate for NEK7 and a development candidate for CDK2, statements around the advancement and application of our 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 59,055	$ 54,912
Marketable securities	119,422	207,914
Other receivables	294	7,656
Prepaid expenses and other current assets	4,140	4,444
Current restricted cash	—	960
Total current assets	182,911	275,886
Property and equipment, net	34,992	27,075
Operating lease right-of-use assets	29,408	34,832
Restricted cash, net of current	4,522	4,318
Other long-term assets	270	278
Total assets	$ 252,103	$ 342,389
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,500	$ 7,862
Accrued expenses and other current liabilities	14,228	14,580
Current portion of operating lease liability	2,881	3,127
Total current liabilities	22,609	25,569
Defined benefit plan liability	1,453	1,533
Operating lease liability	43,517	43,874
Total liabilities	67,579	70,976
Commitments and contingencies		
Stockholders' equity		
Common stock	5	5
Additional paid-in capital	518,610	503,696
Accumulated other comprehensive loss	(1,455)	(1,752)
Accumulated deficit	(332,636)	(230,536)
Total stockholders' equity	184,524	271,413
Total liabilities and stockholders' equity	$ 252,103	$ 342,389

Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 28,306	$ 21,342	$ 84,137	$ 60,193
General and administrative	8,662	7,020	24,311	19,702
Total operating expenses	36,968	28,362	108,448	79,895
Loss from operations	(36,968)	(28,362)	(108,448)	(79,895)
Other income:				
Interest income	2,227	997	6,966	1,774
Foreign currency exchange gain (loss), net	27	63	(151)	293
Gain on disposal of fixed assets	—	(16)	24	109
Loss on sale of marketable securities	—	—	(131)	—
Total other income	2,254	1,044	6,708	2,176
Net loss before income taxes	(34,714)	(27,318)	(101,740)	(77,719)
Provision for income taxes	(170)	—	(360)	—
Net loss	$ (34,884)	$ (27,318)	$ (102,100)	$ (77,719)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.70)	$ (0.58)	$ (2.06)	$ (1.67)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	49,814,903	46,732,353	49,533,143	46,666,000
Net loss	$ (34,884)	$ (27,318)	$ (102,100)	$ (77,719)
Other comprehensive income (loss):				
Provision for pension benefit obligation	14	32	42	99
Unrealized gain (loss) on available-for-sale securities	171	(176)	255	(680)
Comprehensive loss	$ (34,699)	$ (27,462)	$ (101,803)	$ (78,300)

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