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 10, 2022

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.)**

645 Summer Street, Suite 102
Boston, MA 02210
(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 10, 2022, Monte Rosa Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2022. 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 10, 2022.
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 10, 2022

By: /s/ Markus Warmuth

Markus Warmuth

President and Chief Executive Officer

Monte Rosa Therapeutics Reports Third Quarter 2022 Financial Results and Business Updates

– Initiated Patient Dosing in Phase 1/2 Clinical Trial Evaluating MRT-2359, a GSPT1-directed Molecular Glue Degrader, for Treatment of MYC-driven Tumors –

– Progressed VAV1 Molecular Glue Degrader Program into Lead Optimization –

BOSTON, November 10, 2022 – Monte Rosa Therapeutics, Inc. (NASDAQ: GLUE), a biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today reported business highlights and financial results for the third quarter, ended September 30, 2022.

"Throughout 2022, we have made important strides in advancing our QuEEN™ platform and our portfolio of MGDs derived from it, including our GSPT1 degrader MRT-2359. The FDA's clearance of our first investigational new drug application, along with the recent initiation of patient dosing of MRT-2359 in our clinical trial in MYC-driven tumors, serve as strong validation of our platform, the quality of our team and the level of innovation we are bringing to the field," said Markus Warmuth, M.D., CEO of Monte Rosa. "We are continually progressing toward our goal of discovering and developing MGDs into a new generation of precision medicines for patients who currently have no real alternatives. With a strong cash position and investor support, we are well positioned to continue to execute on our first clinical program, as well as advance additional discovery programs through lead optimization."

THIRD QUARTER 2022 & RECENT HIGHLIGHTS

- Received a Study May Proceed Letter from the U.S. Food and Drug Administration (FDA) to begin a Phase 1/2 clinical trial for MRT-2359, a potent, selective and orally bioavailable GSPT1-directed MGD
- Recently initiated patient dosing with MRT-2359, evaluating the treatment of MYC-driven solid tumors, including lung cancer
- Advanced VAV1 degrader program into lead optimization; VAV1 plays a key role in T-cell and B-cell development and activation and is a highly validated target for multiple autoimmune diseases, as well as several types of lymphoma
- Continued progress of CDK2 and NEK7 programs toward development candidate nominations
- Entered into collaboration with Professor Sereina Riniker, Ph.D., (ETH Zürich) to integrate molecular dynamics into Monte Rosa's AI/ML engine for target identification and virtual screening
- Gave multiple presentations at the 5th Annual Targeted Protein Degradation Summit in October in Boston, which included new and updated preclinical data supporting development of MRT-2359 in MYC-driven lung cancer, and novel AI applications for the discovery of MGDs

- Presented overview of development of MRT-2359 as a GSPT1-directed MGD to target MYC-driven malignancies at the 34th EORTC-NCI-AACR Symposium on Oct. 28 in Barcelona, Spain

UPCOMING INVESTOR EVENTS

Monte Rosa will be participating in the following upcoming investor conferences:

- Jefferies 13th Annual Global Healthcare Conference, Nov. 15-17, London
- Piper Sandler 34th Annual Healthcare Conference, Nov. 29-Dec. 1, New York
- 41st Annual J.P. Morgan Health Care Conference, Jan. 9-12, 2023, San Francisco

THIRD QUARTER 2022 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2022 were $21.3 million, compared to $15.1 million for the third quarter of 2021. These increases were due to the expansion of R&D activities, including the advancement of MRT-2359 toward clinical development and the development of the company's QuEEN™ platform and its preclinical programs, as well as increased headcount and laboratory-related expenses due to the company's continued growth as an R&D organization. R&D expenses for the third quarter of 2022 included non-cash stock-based compensation of $1.7 million and non-cash lease expense of $1.5 million due to a rent holiday on the company's Harrison Avenue facility lease. The same period in 2021 included non-cash stock-based compensation expense of $1.1 million.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2022 were $7.0 million, compared to $4.8 million for the third quarter of 2021. The increase in G&A expenses was a result of additional expenses incurred in support of the company's growth and operations as a public company. G&A expenses included non-cash stock-based compensation of $1.5 million for the third quarter of 2022, compared to $1.0 million for the same period in 2021.

Net Loss: Net loss for the third quarter of 2022 was $27.3 million, compared to $19.8 million for the third quarter of 2021.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash and marketable securities as of September 30, 2022, were $277.4 million, compared to cash, cash equivalents and restricted cash of $299.5 million as of June 30, 2022. The decrease is primarily related to cash used to fund operations of $20.6 million and cash used for fixed assets of $1.4 million, partially off-set by proceeds from the exercise of stock options of $0.1 million. The company expects that its cash and cash equivalents will be sufficient to fund planned operations and capital expenditures into late 2024.

About Monte Rosa

Monte Rosa Therapeutics is a biotechnology company developing a portfolio of novel molecular glue degrader (MGD) medicines. These medicines are designed to employ the body's natural

mechanisms to selectively eliminate therapeutically relevant proteins. The company has developed a proprietary protein degradation platform, called QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates), that enables it to rapidly identify protein targets and MGD product candidates that are designed to eliminate therapeutically relevant proteins in a highly selective manner. The company's drug discovery platform combines diverse and proprietary chemical libraries of small molecule protein degraders with in-house proteomics, structural biology, AI/machine learning-based target selection, and computational chemistry capabilities to predict and obtain protein degradation profiles. 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 in herein include, but are not limited to, statements about our product development activities, including our expectations around MRT-2359 and the ongoing development of our QuEEN™ platform, and the advancement of our pipeline and the various products therein, , our expectations of timing for of our clinical trial for MRT-2359, our ability to initiate and the timing of initiation of additional lead optimization programs, and our expectations regarding our ability to nominate and the timing of our nominations of additional development candidates. By their nature, these statements are subject to numerous risks and uncertainties, including the impact that the current COVID-19 pandemic will have on our development activities and operations, as well as those risks and uncertainties set forth in our most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K for the year ended December 31, 2021 filed with the US Securities and Exchange Commission, 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 and per share amounts)
(unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 112,394	$ 346,071
Marketable securities	159,755	—
Proceeds receivable from common stock sale	13,507	—
Other receivables	4,050	—
Prepaid expenses and other current assets	4,569	2,595
Current restricted cash	960	—
Total current assets	295,235	348,666
Property and equipment, net	19,384	12,325
Operating lease right-of-use assets	38,534	—
Restricted cash, net of current	4,302	5,338
Other long-term assets	148	—
Total assets	$ 357,603	$ 366,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,753	$ 6,558
Accrued expenses and other current liabilities	8,972	10,080
Current portion of operating lease liability	3,065	—
Total current liabilities	21,790	16,638
Defined benefit plan liability	2,128	2,176
Operating lease liability	42,593	—
Total liabilities	66,511	18,814
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 48,528,247 shares issued and 48,372,781 shares outstanding as of September 30, 2022; and 500,000,000 shares authorized, 46,794,295 shares issued and 46,535,966 shares outstanding as of December 31, 2021	5	5
Additional paid-in capital	493,443	471,566
Accumulated other comprehensive loss	(2,602)	(2,021)
Accumulated deficit	(199,754)	(122,035)
Total stockholders' equity	291,092	347,515
Total liabilities and stockholders' equity	$ 357,603	$ 366,329

Consolidated Statement of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended September 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 21,342	$ 15,115
General and administrative	7,020	4,753
Total operating expenses	28,362	19,868
Loss from operations	(28,362)	(19,868)
Other income:		
Interest income, net	997	13
Foreign currency exchange gain, net	63	18
Loss on disposal of fixed assets	(16)	—
Total other income	1,044	31
Net loss	$ (27,318)	$ (19,837)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.58)	$ (0.43)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	46,732,353	45,987,866

Contacts:

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