Monte Rosa Therapeutics Announces Third Quarter 2025 Financial Results and Business Updates

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Second agreement signed with Novartis to develop novel degraders for immune-mediated diseases, providing upfront payment of $120 million plus option maintenance payments, and eligibility for option exercise payments, milestones, and tiered royalties

Phase 1 study of NEK7-directed MGD MRT-8102 underway, investigating a potential novel approach to treat inflammatory diseases driven by the NLRP3 inflammasome; initial readout including data from high-CVD risk cohort on track for H1 2026

VAV1-directed MGD MRT-6160 advancing toward anticipated initiation of multiple Phase 2 studies in immune-mediated diseases

Phase 1/2 study of GSPT1-directed MGD MRT-2359 advancing in heavily pretreated, metastatic castration-resistant prostate cancer (mCRPC) patients; additional results expected by year-end

Strong cash position expected to fund operations through 2028, enabling multiple anticipated proof-of-concept clinical readouts across the portfolio

BOSTON, Nov. 06, 2025 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2025.

“With three programs in clinical development and a highly productive drug discovery engine creating additional future opportunities, we are building a leading protein degradation company innovating in the molecular glue degrader space,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “In that context, our recently announced second collaboration with Novartis marks another major milestone for Monte Rosa, significantly expanding our potential impact on immune-mediated diseases. We believe this partnership further validates the breadth and versatility of our QuEEN™ discovery engine and underscores the growing recognition of MGDs as a distinct and potentially transformative therapeutic modality. Our cash runway extends beyond multiple anticipated Phase 2 readouts for MRT-8102, MRT-6160, and MRT-2359, and positions us to execute on our early-stage portfolio, including multiple undisclosed targets in Th1, Th2, and Th17-driven autoimmune conditions.”

“In regard to our clinical programs, we are enrolling our Phase 1 study of MRT-8102, the only clinical-stage degrader targeting NEK7, which we believe offers a highly differentiated approach to potentially address a wide range of inflammatory and cardio-immunology indications driven by the NLRP3 inflammasome, IL-1β and IL-6. We have recently initiated dosing a cohort of subjects with elevated cardiovascular disease (CVD) risk to evaluate changes in well-validated biomarkers such as C-reactive protein. Initial MRT-8102 data from the healthy volunteer and elevated CVD-risk subject cohorts are on track for the first half of 2026. In addition, we continue to work with Novartis to advance MRT-6160, our VAV1-directed MGD, towards Phase 2 studies across multiple indications where alternative treatment options are urgently needed. Our recent preclinical data presentation at ACR Convergence provides further support for exploration of systemic lupus erythematosus, Sjögren's disease, and rheumatoid arthritis, amongst others. In oncology, MRT-2359 continues to progress through expansion in mCRPC, and we plan to share additional data by year-end. We are also making strong progress with our programs targeting cyclin E1 and CDK2, two well-validated tumor drivers poorly addressed by conventional approaches, and we remain on track for an Investigational New Drug (IND) submission next year.”

RECENT HIGHLIGHTS

Collaboration with Novartis for degraders to treat immune-mediated diseases

- In September 2025, Monte Rosa announced a second agreement to collaborate with Novartis to develop novel degraders for immune-mediated diseases. Monte Rosa’s publicly disclosed pipeline programs are outside the scope of this agreement.
- Under the terms of the agreement, Monte Rosa has received 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.

MRT-8102, NEK7-directed MGD for inflammatory diseases driven by IL-1β, IL-6, and the NLRP3 inflammasome

- Monte Rosa continues to execute a Phase 1 study of MRT-8102, a first-in-class, NEK7-directed MGD for inflammatory diseases driven by the NLRP3 inflammasome, IL-1β, and IL-6. The ongoing study includes single ascending dose / multiple ascending dose (SAD/MAD) cohorts in healthy volunteers, as well as an additional Part 3 cohort designed to evaluate potential early proof of concept in subjects with increased CVD risk. The Company has initiated dosing in Part 3 of the study, evaluating subjects with high CVD risk. Initial Phase 1 data, including from the Part 3 cohort, are on track for H1 2026.

MRT-6160, VAV1-directed MGD for immune-mediated conditions

- Advancement of MRT-6160 toward multiple Phase 2 studies in immune-mediated diseases is ongoing, in collaboration with Novartis. Results from the Phase 1, SAD/MAD study in healthy volunteers (clinicaltrials.gov identifier NCT06597799) support a clear path into anticipated Phase 2 studies and broad potential applications in multiple immune-mediated diseases.
- In October, Monte Rosa presented additional preclinical data at ACR Convergence 2025, demonstrating that in a spontaneous autoimmune disease mouse model characterized by chronic inflammation, autoantibody production, and multi-organ involvement, MRT-6160 inhibited disease pathology, including proteinuria, lymphadenopathy, skin lesion formation, autoantibody production, and organomegaly. These results provide further support for MRT-6160's potential across multiple immune-mediated diseases, including systemic lupus erythematosus, Sjögren's disease, rheumatoid arthritis, and others.
- Monte Rosa has a global exclusive development and commercialization license agreement with Novartis to advance VAV1-directed MGDs, including MRT-6160. Monte Rosa is eligible to receive up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies. Novartis is responsible for conducting and funding Phase 2 studies. Monte Rosa will co-fund any Phase 3 clinical development and will share 30% of any profits and losses associated with the manufacturing and commercialization of MRT-6160 in the U.S., and is also eligible for tiered royalties on ex-U.S. net sales.

MRT-2359, GSPT1-directed MGD for MYC-driven solid tumors

- Monte Rosa continues to enroll and evaluate MRT-2359 in patients with mCRPC. The Company plans to present updated clinical results in 20 to 30 patients with mCRPC and in patients with hormone receptor (HR)+ breast cancer by year-end 2025.

Cyclin E1 and CDK2-directed MGD programs for treatment of solid tumors

- Monte Rosa continues to advance its cyclin E1 (CCNE1)- and CDK2-directed MGD programs for the treatment of CCNE1-amplified solid tumors and ER+ breast cancer toward clinical development. The Company remains on track to submit an IND application in 2026 for a CDK2 and/or cyclin E1-directed MGD.

QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) discovery engine

- In July 2025, Monte Rosa's publication, featured on the cover of *Science*, showcased the Company's proprietary QuEEN™ AI/ML-powered discovery engine. The findings significantly expand the targetable protein space for MGD drug discovery, unlocking new opportunities to address previously undruggable therapeutic targets.
- Monte Rosa continues to progress its strategic collaboration with Roche to discover and develop MGDs against targets in cancer and neurological diseases previously considered impossible to drug.

ANTICIPATED UPCOMING MILESTONES AND DEVELOPMENT PRIORITIES

Immunology and Inflammation disease programs

- Continue advancement of MRT-6160 toward Phase 2 initiation, in collaboration with Novartis.
- Share MRT-8102 Phase 1 results in H1 2026.
- Submit an IND application for a second-generation NEK7-directed MGD with enhanced CNS penetration in 2026.

Oncology programs

- Share updated MRT-2359 Phase 1/2 study data in heavily pretreated mCRPC patients and in patients with HR+ breast cancer by year-end 2025.
- Submit an IND application for a CDK2 and/or cyclin E1-directed MGD in 2026.

THIRD QUARTER 2025 FINANCIAL RESULTS

Collaboration Revenue: Collaboration revenue for the third quarter of 2025 was $12.8 million, compared to $9.2 million for the third quarter of 2024. Collaboration revenue represents amounts earned from our collaboration and license agreements with Roche and Novartis.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2025 were $36.7 million, compared to $27.6 million for the third quarter of 2024. These increases were driven by the successful achievement of key milestones in our R&D organization, including the advancement of MRT-8102 to enter the clinic, the continuation of the MRT-2359 clinical study, continued program activities for MRT-6160 in preparation for Phase 2 studies, the progression of our preclinical pipeline, including research performed in connection with our collaboration with Roche, and the continued development of the Company's QuEEN™ discovery engine. Non-cash stock-based compensation constituted $2.5 million of R&D expenses for the third quarter of 2025, compared to $2.6 million in the same period in 2024.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2025 were $9.1 million compared to $8.1 million for the third quarter of 2024. G&A expenses included non-cash stock-based compensation of $1.9 million for the third quarter of 2025, compared to $1.7 million in the same period in 2024.

Net Loss: Net loss for the third quarter of 2025 was $27.1 million, compared to a net loss of $23.9 million for the third quarter of 2024.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2025, were $396.2 million, compared to cash, cash equivalents, restricted cash, and marketable securities of $295.5 million as of June 30, 2025. The increase of $100.7 million was primarily due to a $120.0 million non-refundable upfront payment the Company received from Novartis in September 2025. The Company also received from Novartis $9.7 million for value added taxes related to the transaction, which is included in the Company's accounts payable balance as of September 30, 2025 and is expected to be remitted to the Swiss government in the fourth quarter of 2025. During October 2025, the Company sold 2,955,082 shares of common stock in an at-the-market offering for aggregate gross proceeds of $25.0 million, or aggregate net proceeds of $23.9 million after deducting sales agent discounts, commissions, and other offering costs.

Based on current cash, cash equivalents, restricted cash, marketable securities, and certain anticipated Roche and Novartis collaboration revenue, the Company expects its cash and cash equivalents to be sufficient to fund planned operations and capital expenditures through 2028.

About MRT-6160

MRT-6160 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader of VAV1, which in preclinical studies has shown deep degradation of its target with no detectable effects on other proteins. VAV1 is a key signaling protein downstream of both the T- and B-cell receptors. VAV1 expression is restricted to immune cells, including T and B cells. MRT-6160 has shown promising activity in preclinical models of multiple immune-mediated conditions. In a Phase 1, single ascending dose / multiple ascending dose (SAD/MAD) study in healthy subjects (clinicaltrials.gov identifier NCT06597799), MRT-6160 demonstrated sustained, dose-dependent VAV1 degradation in peripheral blood T and B cells after single and multiple dose administration. MRT-6160 also substantially inhibited secretion of inflammatory cytokines from whole blood derived T and B cells following *ex vivo* stimulation. Under the terms of an agreement announced in October 2024, Novartis has exclusive worldwide rights to develop, manufacture and commercialize MRT-6160 and other VAV1 MGDs. Monte Rosa is eligible to receive up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies. 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., and is also eligible for tiered royalties on ex-U.S. net sales.

About MRT-8102

MRT-8102 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader (MGD) that targets NEK7 for the treatment of inflammatory diseases linked to NLRP3, IL-1β, and IL-6 dysregulation. NEK7 has been shown to be required for NLRP3 inflammasome assembly, activation and IL-1β release both *in vitro* and *in vivo*. Aberrant NLRP3 inflammasome activation and the subsequent release of active IL-1β and interleukin-18 (IL-18) has been implicated in multiple inflammatory disorders, including cardiovascular disease, gout, osteoarthritis, neurologic disorders including Parkinson's disease and Alzheimer's disease, and metabolic disorders. In a non-human primate model, MRT-8102 was shown to potently, selectively, and durably degrade NEK7, and resulted in near-complete reductions of IL-1β and caspase-1 following *ex vivo* stimulation of whole blood. MRT-8102 has demonstrated a considerable safety margin (>200-fold exposure margin over projected human efficacious dose) in GLP toxicology studies. MRT-8102 is currently being investigated in a Phase 1 study (clinicaltrials.gov identifier NCT07119125) in healthy participants and participants at elevated cardiovascular disease risk.

About MRT-2359

MRT-2359 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader (MGD) of GSPT1. 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. MRT-2359 is being investigated in an ongoing Phase 1/2 study (clinicaltrials.gov identifier NCT05546268) in solid tumors,

including castration-resistant prostate cancer (CRPC). In heavily pretreated CRPC patients, a patient group characterized by widespread expression of c-MYC, MRT-2359 demonstrated encouraging early signals of clinical response.

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. 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 first-in-class and only-in-class MGDs, spanning autoimmune and inflammatory diseases, oncology, and beyond, with three programs in the clinic. Monte Rosa has ongoing collaborations with leading pharmaceutical companies in the areas of immunology, oncology and neurology. 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 ability to grow our product pipeline, our ability to successfully complete research and further development and commercialization of our drug candidates in current or future indications, including the timing and results of our clinical trials and our ability to conduct and complete clinical trials, statements regarding our progress and speed of development of only-in-class and first-in-class molecular glue degrader therapeutics, statements around the Company's QuEEN™ discovery engine and the broad potential applications of the platform and the Company's ability to create long-term value through focused pipeline execution and strategic collaborations, as well as to expand the targetable protein space for MGD drug discovery, unlocking new opportunities to address previously undruggable therapeutic targets, statements about the Company's view of its potential to rationally design MGDs with unprecedented selectivity and its potential impact on immune-mediated diseases, statements around the breadth and versatility of our QuEEN™ discovery engine and the growing recognition of MGDs as a distinct and potentially transformative therapeutic modality, statements about the advancement and timeline of our preclinical and clinical programs, pipeline and the various products therein, including (i) the ongoing development of our VAV1-directed degrader, referred to as MRT-6160, statements related to its clear path into anticipated Phase 2 studies in collaboration with Novartis and our expectations regarding the broad potential applications in multiple immune-mediated diseases, including systemic lupus erythematosus, Sjögren's disease, rheumatoid arthritis, and others, (ii) the ongoing development and progress of our NEK7-directed MGD, referred to as MRT-8102, including our expectations regarding initial Phase 1 data in the first half of 2026 and statements regarding our beliefs that MRT-8102 offers a highly differentiated approach to potentially address a wide range of inflammatory and cardio-immunology indications, (iii) the ongoing development of a second-generation NEK7-directed MGD optimized for CNS penetration and our statements around expected IND submission in 2026, and (iv) our ongoing clinical development of MRT-2359, statements regarding the timing for data readouts by year-end 2025 and around MRT-2359's potential to provide therapeutic benefit to patients resistant to androgen receptor inhibitors, including those with AR alterations, as well as statements related to the expected potential clinical benefit of any of our candidates, advancement and application of our platform, statements around our ability to capitalize on and potential benefits resulting from our research and translational insights, including announcements related to preclinical programs, as well as our the ability to optimize collaborations with industry partners on our development programs, statements about obligations under our collaboration agreements, expectations around the receipt of any payments under such agreements and the future development and commercialization of various products, statements regarding regulatory filings for our development programs, including the planned timing of such regulatory filings, such as IND applications, and potential review by regulatory authorities, our use of capital, expenses and other financial results in the future, availability of funding for existing programs, ability to fund operations through 2028 beyond multiple anticipated Phase 2 readouts for MRT-8102, MRT-6160, and MRT-2359, statements around our cash runway positioning us to execute on our early-stage portfolio including multiple undisclosed targets in Th1, Th2, and Th17-driven autoimmune conditions, statements around our expectations of success for our programs, strength of collaboration relationships 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, 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.

Condensed Consolidated Balance Sheets
(in thousands, except share amounts)
(unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 208,343	$ 224,254
Marketable securities	182,915	147,895
Other receivables	4,965	173
Prepaid expenses and other current assets	5,594	5,118
Total current assets	401,817	377,440
Property and equipment, net	27,598	29,483
Operating lease right-of-use assets	25,065	26,831
Restricted cash	4,950	4,863
Other long-term assets	411	115
Total assets	$ 459,841	$ 438,732
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,509	$ 17,215
Accrued expenses and other current liabilities	17,902	18,785
Current deferred revenue	24,791	117,232
Current portion of operating lease liability	4,241	3,714
Total current liabilities	61,443	156,946
Deferred revenue, net of current	111,894	16,147
Defined benefit plan liability	4,740	3,702
Operating lease liability, net of current	35,927	39,001
Total liabilities	214,004	215,796
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 61,790,239 and 61,507,446 shares issued and outstanding as of September 30, 2025 and December 31, 2024 respectively	6	6
Additional paid-in capital	680,157	664,874
Accumulated other comprehensive loss	(3,247)	(3,356)
Accumulated deficit	(431,079)	(438,588)
Total stockholders' equity	245,837	222,936
Total liabilities and stockholders' equity	$ 459,841	$ 438,732

Condensed Consolidated Statements of Operations
(in thousands)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 12,768	$ 9,216	$ 120,891	$ 14,975
Operating expenses:				
Research and development	36,678	27,616	99,521	82,697
General and administrative	9,065	8,127	25,863	26,394
Total operating expenses	45,743	35,743	125,384	109,091
Loss from operations	(32,975)	(26,527)	(4,493)	(94,116)
Other income:				
Interest income	2,746	2,892	9,253	7,971

Foreign currency exchange (loss) gain, net	(29)	(153)	1,534	414
Gain on disposal of property and equipment	—	—	59	—
Total other income	2,717	2,739	10,846	8,385
Net (loss) income before income taxes	$ (30,258)	$ (23,788)	$ 6,353	$ (85,731)
Income tax benefit (provision)	3,177	(71)	1,156	(406)
Net (loss) income	$ (27,081)	$ (23,859)	$ 7,509	$ (86,137)

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