Monte Rosa Therapeutics Announces Fourth Quarter and Full-Year 2025 Financial Results and Business Updates

3.17.2026

Positive interim Phase 1 data of NEK7-directed MGD MRT-8102 demonstrated profound CRP reductions in elevated CVD-risk subjects; readout of expanded part 3 CRP PoC trial (now called GFORCE-1) anticipated in H2 2026

Newly announced unblinded safety data from MRT-8102 SAD/MAD cohorts continue to support favorable safety/tolerability profile and wide therapeutic window

Company plans to initiate multiple Phase 2 studies of MRT-8102, including in patients with elevated CVD-risk in H2 2026, in patients with gout flares in Q4 2026/Q1 2027, and in patients with moderate to severe hidradenitis suppurativa in H1 2027

Presented positive interim data from the Phase 1/2 clinical study of MRT-2359 in combination with enzalutamide showing 100% PSA response rate in metastatic castration-resistant prostate cancer (mCRPC) patients with AR mutations

Phase 2 study initiation of MRT-2359 in combination with apalutamide in mCRPC patients with AR mutations anticipated in Q3 2026

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

$345 million upsized follow-on financing further strengthens balance sheet, supporting operations into 2029 and through multiple anticipated Phase 2 study initiations and clinical data readouts

BOSTON, March 17, 2026 (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 fourth quarter and full year ended December 31, 2025.

“Monte Rosa is now on the cusp of Phase 2 trial initiations for three clinical-stage programs, each targeting expansive opportunities. Strengthened by our recent capital raise, our cash runway now extends into 2029 and enables us to fund aggressive development plans for each of our programs through multiple anticipated readouts and value inflection points,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “We recently presented clinical data from the Phase 1 study of our NEK7-directed MGD MRT-8102, demonstrating suppression of high-sensitivity C-reactive protein (hsCRP) at rates comparable to or better than those previously reported with biologic therapies, supporting the potential of MRT-8102 to be an oral best-in-class therapeutic among agents targeting the NLRP3/IL-1/IL-6 pathway. The unblinded SAD/MAD safety data announced today, combined with the recently announced 3-month results from our long-term cynomolgus (cyno) monkey toxicology study, further support the favorable safety/tolerability profile observed to date and wide therapeutic window of this drug candidate. In addition, today we released promising data from a cyno obesity study demonstrating substantial impact of NEK7 degradation on body weight and body fat composition, alone or in combination with semaglutide.”

“Our preclinical and clinical data corroborate the important role of NEK7 in driving lipid and metabolite-induced inflammation and support further development of MRT-8102 in cardiovascular and cardiometabolic indications,” said Filip Janku, M.D., Ph.D., Chief Medical Officer of Monte Rosa Therapeutics. “Dosing is underway in our expanded GFORCE-1 study in subjects with elevated cardiovascular disease (CVD) risk, with additional results expected in H2 2026, and we look forward to initiating multiple Phase 2 studies of MRT-8102, starting with an ASCVD study this year. We’re excited that our VAV1-directed MGD MRT-6160, in collaboration with Novartis, is advancing towards multiple Phase 2 study initiations in immune-mediated diseases. Additionally, based on the promising data from our Phase 1/2 study of MRT-2359 in combination with an AR inhibitor in mCRPC patients, we plan to initiate a new Phase 2 study this year to evaluate MRT-2359 in combination with the second-generation AR-inhibitor apalutamide in patients with AR mutations, a population with limited therapeutic options. We are very pleased to have entered into a supply agreement with Johnson & Johnson for the provision of apalutamide for this study.”

RECENT HIGHLIGHTS

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

- In January, Monte Rosa announced positive interim data from an ongoing Phase 1 clinical study evaluating MRT-8102. In subjects with elevated cardiovascular disease (CVD) risk, MRT-8102 demonstrated rapid and durable reductions in systemic inflammation. After four weeks of MRT-8102 administration, CRP levels decreased by 85%, and 94% of study

participants achieved CRP levels below 2 mg/L, a threshold associated with reduced CVD risk. Single ascending dose (SAD) and multiple ascending dose (MAD) cohorts demonstrated deep and sustained NEK7 degradation at doses from 5 mg to 400 mg.
- Monte Rosa today announced unblinded safety data from the SAD/MAD cohorts of the Phase 1 study. In a total of 88 participants treated, there were no serious adverse events (SAEs), and no treatment-emergent adverse events (AEs) over grade 2. Rates of treatment-emergent AEs were 29% in subjects treated with MRT-8102, compared with 32% in subjects treated with placebo. The most frequent treatment-emergent AE was headache, reported in 9% of participants treated with MRT-8102 and 9% of participants treated with placebo. The data support a broad therapeutic index for MRT-8102.
- Monte Rosa recently provided topline 3-month results from the ongoing long-term toxicology study in cynos. No test article-related findings were reported and the no observed adverse events level (NOAEL) was the highest dose tested, a dose approximately 200 – 300-fold over the projected human efficacious dose. These findings reinforce the favorable safety and tolerability profile observed to date in the ongoing Phase 1 clinical study of MRT-8102 and in the 28-day preclinical GLP toxicology studies.
- In a cyno model of high-fat diet-induced obesity, daily dosing of a NEK7 MGD for 11 weeks produced an approximately 8% reduction in body weight relative to vehicle-treated animals. When combined with the GLP-1 receptor agonist semaglutide, body weight loss exceeded 23% relative to the vehicle group (versus 17% for semaglutide monotherapy). These findings are consistent with similar studies conducted with MRT-8102, both alone and in combination with semaglutide, in a mouse model of high-fat diet-induced obesity. Notably, DEXA body composition analysis of the cynos revealed preferential reductions in central abdominal fat, a depot strongly associated with increased metabolic risk, with proportionally greater loss compared with the gynoid fat depot and minimal impact on lean mass.
- As announced in January, the ongoing GFORCE-1 Study of MRT-8102 in subjects with elevated CVD risk has been expanded to multiple dose levels to accelerate development in atherosclerotic cardiovascular disease (ASCVD) with an anticipated readout in H2 2026. Dosing is now ongoing in the additional dose cohorts.
- Monte Rosa expects to initiate multiple Phase 2 studies of MRT-8102 in indications with high unmet need and strong biologic rationale for targeting the NLPR3/IL-1/IL-6 pathway:
    - A study (GFORCE-2) of MRT-8102 in elevated CVD risk patients defined by Stage 3/4 chronic kidney disease and elevated CRP, expected to initiate in H2 2026, to evaluate the effect of MRT-8102 treatment for 12 weeks (plus open-label extension) on CRP levels, as well as effects on liver fat, liver inflammation, and obesity
    - A study (GFORCE-3) of MRT-8102 in patients with gout flares, expected to initiate in Q4 2026 or Q1 2027
    - A study (GFORCE-4) of MRT-8102 in patients with moderate to severe hidradenitis suppurativa, expected to initiate in H1 2027

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, single ascending dose / multiple ascending dose (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 supportive MRT-6160 preclinical data at ACR Convergence 2025. In a preclinical autoimmune disease model characterized by chronic inflammation, autoantibody production, and multi-organ involvement, administration of MRT-6160 resulted in broad activity across an array of disease markers, including attenuated autoantibody levels and reduced skin and kidney pathology.
- 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 metastatic CRPC

- In February, Monte Rosa announced additional interim data from an ongoing Phase 1/2 clinical study evaluating MRT-2359 in combination with enzalutamide in heavily pretreated patients with mCRPC. MRT-2359 is an investigational, orally bioavailable, GSPT1-directed MGD. PSA responses in patients with AR mutations expanded to 5 of 5 patients, with a 100% disease control rate, including 2 patients with RECIST partial responses and 3 with stable disease, all showing reductions in size of target lesions. Across all 15 evaluable patients, the overall RECIST disease control rate was 67%, and 10 of 15 patients showed tumor size reductions of target lesions. The combination of MRT-2359 and enzalutamide was generally well-tolerated with primarily Grade 1-2 AEs. There were no treatment discontinuations due to AEs. The data bolster the promising results shared in December, reinforcing MRT-2359's potential in mCRPC.
- The Company plans to initiate a Phase 2 study in 2026 of up to 25 patients to efficiently assess the efficacy of MRT-2359 in combination with the second-generation AR inhibitor apalutamide in mCRPC patients with AR mutations, with potential to expand the study into additional patient subsets.
- In March, Monte Rosa announced it entered into a supply agreement with Johnson & Johnson to evaluate MRT-2359 in combination with ERLEADA® (apalutamide) for the treatment of patients with mCRPC with androgen receptor (AR) mutations in its planned Phase 2 study.

Cyclin E1 and CDK2-directed MGD programs for 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 expects to submit an IND application in 2026 for a cyclin E1-directed MGD.

Corporate

- In January, Monte Rosa closed an upsized underwritten public offering of 13,000,000 shares of its common stock, including the full exercise by the underwriters of their option to purchase an additional 1,875,000 shares, at a public offering price of $24.00 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,375,000 shares of common stock at a public offering price of $23.9999 per pre-funded warrant, which represents the per share public offering price of each share of common stock less the $0.0001 per share exercise price for each pre-funded warrant. The gross proceeds to Monte Rosa from the offering, before deducting underwriting discounts and commissions and offering expenses, were approximately $345 million. All of the shares and pre-funded warrants in the offering were sold by Monte Rosa.
- 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 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.
- In December 2025, Monte Rosa achieved a preclinical milestone under its strategic collaboration and license agreement with Roche, triggering a $7 million milestone payment to Monte Rosa.
- Monte Rosa today announced two leadership team promotions: Magnus Walter, DPhil, to Chief Technology Officer, and Andrew Funderburk to Chief Investor Relations and Strategy Officer.

ANTICIPATED UPCOMING MILESTONES AND DEVELOPMENT PRIORITIES
Immunology and Inflammation disease programs

- Readout of MRT-8102 GFORCE-1 study in subjects with elevated CVD risk anticipated in H2 2026.
- Initiate multiple Phase 2 studies of MRT-8102, including in elevated CVD risk patients with Stage 3/4 chronic kidney disease in H2 2026, in gout flare patients in Q4 2026/Q1 2027, and in hidradenitis suppurativa patients in H1 2027.
- Submit an IND application for a second-generation NEK7-directed MGD in 2026.
- Monte Rosa expects its collaborator, Novartis, to initiate multiple Phase 2 studies of VAV1-directed MGD MRT-6160 in immune-mediated diseases in 2026.

Oncology programs

- Initiate the MODeFIRe-1 Phase 2 study of MRT-2359 in combination with apalutamide in mCRPC in Q3 2026.
- Submit an IND application for a cyclin E1-directed MGD in 2026.

FOURTH QUARTER AND FULL YEAR 2025 FINANCIAL RESULTS

Collaboration Revenue: Collaboration revenue for the fourth quarter of 2025 was $2.8 million, compared to $60.6 million for the fourth quarter of 2024, and $123.7 million for the year ended December 31, 2025, as compared to $75.6 million for the year ended December 31, 2024. Collaboration revenue represents amounts earned from the Company's collaboration and license agreements with Roche and Novartis.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2025 were $42.0 million, compared to $38.9 million for the fourth quarter of 2024, and $141.5 million for the year ended December 31, 2025, compared to $121.6 million for the year ended December 31, 2024. These increases were driven by increased spending during the year on our MRT-8102 program and on other development and discovery programs.

General and Administrative (G&A) Expenses: G&A expenses for the fourth quarter of 2025 were $10.5 million compared to $8.8 million for the fourth quarter of 2024, and $36.4 million for the year ended December 31, 2025, compared to $35.2 million for the year ended December 31, 2024. These increases, which include non-cash stock-based compensation, were driven by increased headcount and expenses in support of our growth and operations as a public company.

Net Loss: Net loss for the fourth quarter of 2025 was $46.1 million, compared to $13.4 million for the fourth quarter of 2024, and net loss for the year ended December 31, 2025, was $38.6 million, compared to $72.7 million for the year ended December 31,

2024.

Cash Position and Financial Guidance:
Cash, cash equivalents, restricted cash, and marketable securities as of December 31, 2025, were $382.1 million, compared to cash, cash equivalents, restricted cash, and marketable securities of $396.2 million as of September 30, 2025. The decrease of $14.1 million was primarily due to operational use of cash, partially offset by proceeds of $24.3 million from the sale of stock under our at-the-market program.

In January 2026, the Company closed an underwritten public equity offering of approximately $345.0 million aggregate gross proceeds. Aggregate net proceeds from the offering after deducting underwriting discounts and commissions and offering expenses are expected to be approximately $323.8 million.

Based on current cash, cash equivalents, restricted cash, and marketable securities, together with the proceeds from the 2026 Offering, the Company expects its cash and cash equivalents to be sufficient to fund planned operations and capital expenditures into 2029.

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, statements about the Company's view of its potential to rationally design MGDs with unprecedented selectivity, 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, as well as our expectation that our collaborator, Novartis, will initiate multiple Phase 2 studies of VAV1-directed MGD MRT-6160 in immune-mediated diseases in 2026 (ii) the ongoing development and progress of our NEK7-directed MGD, referred to as MRT-8102, including our expectations regarding anticipated readout of data of the GFORCE-1 study in subjects with elevated CVD risk in H2 2026, as well as our expectations to initiate multiple Phase 2 studies of MRT-8102, including in elevated CVD risk patients with Stage 3/4 chronic kidney disease in H2 2026, in gout flare patients in Q4 2026/Q1 2027, and in hidradenitis suppurativa patients in H1 2027, statements around additional indications for Phase 2 studies of MRT-8102, including hidradenitis suppurativa and statement around MRT-8102's potential to be an oral best-in-class therapeutic among agents targeting the NLRP3/IL-1/IL-6 pathway and statements relating to demonstrating suppression of high-sensitivity C-reactive protein (hsCRP) at rates comparable to or better than those previously reported with biologic therapies, (iii) the ongoing development of a second-generation NEK7-directed MGD with enhanced CNS penetration and our statements around expected IND submission in 2026, (iv) our ongoing clinical development of MRT-2359, statements relating our expectations to initiate the MODeFIRe-1 Phase 2 study of MRT-2359 in combination with the second-generation androgen receptor inhibitor apalutamide in mCRPC in Q3 2026,5 and (v) statements around the progress of both our CDK2 and cyclin E1-directed MGD programs, including statements around the timing of submission of an IND application in 2026 for a cyclin E1-directed MGD, 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 through multiple anticipated Phase 2 study initiations and clinical data readouts, ability to fund operations and capital expenditures into 2029, as well as 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, 2025, filed with the U.S. Securities and Exchange Commission on March 17, 2026, 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)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 129,883	$ 224,254
Marketable securities	247,221	147,895
Collaboration receivable	7,000	—
Other receivables	4,600	173
Prepaid expenses and other current assets	4,481	5,118
Total current assets	393,185	377,440
Property and equipment, net	25,986	29,483
Operating lease right-of-use assets	24,386	26,831
Restricted cash	4,954	4,863
Other long-term assets	148	115
Total assets	$ 448,659	$ 438,732
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,550	$ 17,215
Accrued expenses and other current liabilities	26,694	18,785
Current deferred revenue	29,571	117,232
Current portion of operating lease liability	4,397	3,714
Total current liabilities	64,212	156,946
Deferred revenue, net of current	111,332	16,147
Defined benefit plan liability	5,265	3,702
Operating lease liability, net of current	34,794	39,001
Total liabilities	215,603	215,796
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 65,543,723 and 61,507,446 shares issued and outstanding as of December 31, 2025 and 2024, respectively	7	6
Additional paid-in capital	714,090	664,874
Accumulated other comprehensive loss	(3,827)	(3,356)
Accumulated deficit	(477,214)	(438,588)
Total stockholders' equity	233,056	222,936
Total liabilities and stockholders' equity	$ 448,659	$ 438,732

Condensed Consolidated Statements of Operations
(In thousands)

	Three months ended December,		Year ended December 31,	
	2025	2024	2025	2024
Collaboration revenue	$ 2,781	$ 60,647	$ 123,672	$ 75,622
Operating expenses:				
Research and development	41,979	38,866	141,500	121,563
General and administrative	10,517	8,777	36,380	35,171
Total operating expenses	52,496	47,643	177,880	156,734
(Loss) income from operations	(49,715)	13,004	(54,208)	(81,112)
Other income:				
Interest income	3,689	2,595	12,942	10,566
Foreign currency exchange (loss) gain, net	(50)	2	1,484	416
Gain on disposal of property and equipment	—	—	59	—
Total other income	3,639	2,597	14,485	10,982
Net (loss) income before income taxes	$ (46,076)	$ 15,601	$ (39,723)	$ (70,130)
Income tax (provision) benefit	(59)	(2,164)	1,097	(2,570)
Net (loss) income	$ (46,135)	$ 13,437	$ (38,626)	$ (72,700)

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