Monte Rosa Therapeutics Announces Third Quarter 2026 Financial Results and Business Updates

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Positive GFORCE-1 Phase 1 results showed MRT-8102 reduced key pathogenic drivers of atherosclerotic cardiovascular disease (ASCVD) to levels comparable to healthy volunteers across all three dose levels, with treatment-emergent adverse event rates comparable to placebo; Phase 2 initiation in coronary artery disease anticipated in H1 2027

Initiation of Phase 2 study of MRT-8102 in gout expected in Q4 2026, with data update expected in H2 2027; additional Phase 2 initiation in hidradenitis suppurativa anticipated in H1 2027

Initiated MODeFIRe-1 Phase 2 study of MRT-2359 in combination with apalutamide in heavily pretreated metastatic castration-resistant prostate cancer (mCRPC) patients with androgen receptor (AR) mutations; Phase 2 data update expected in 2027; updated Phase 1/2 study data expected this year

Novartis initiated Phase 2a/b studies of VAV1-directed MGD MRT-6160 (DDY391) in Sjögren's disease and psoriatic arthritis, triggering a total of $87.5 million in Phase 2 milestone payments to date to Monte Rosa

Strong balance sheet with cash, cash equivalents, restricted cash, and marketable securities of $582.6 million (not including MRT-6160 Phase 2 initiation milestones) as of September 30, 2026, expected to support operations into 2029

BOSTON, Nov. 05, 2026 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced business highlights and financial results for the third quarter ended September 30, 2026.

"The last quarter marks a tremendously important step forward for our clinical portfolio, with a positive readout from the GFORCE-1 study of MRT-8102, the initiation of Phase 2 development for MRT-2359, and the advancement of our partnered VAV1 program into two Phase 2 studies," said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. "The GFORCE-1 results reinforce our view that targeting NEK7 at the top of the NLRP3 signaling cascade could address a broader set of disease drivers than targeting individual downstream cytokines. Our planned Phase 2 studies in coronary artery disease (CAD), gout, and hidradenitis suppurativa, conditions with major unmet needs, are intended to deepen our understanding of the therapeutic potential of NEK7 degradation. In CAD, our innovative study design integrates molecular and imaging-based readouts to explore how MRT-8102's broad biological activity translates into changes in coronary plaque biology, to inform patient selection and design for an efficient future Phase 3 study."

Dr. Warmuth continued: "We are particularly excited about the opportunity in gout, where there is a substantial unmet need for effective flare prevention that is well tolerated with prolonged use. With the emergence of next-generation urate-lowering drugs and their propensity to induce flares in the first 6 to 12 months of use, we believe the need for a well-tolerated, non-immunosuppressive flare prevention treatment will only increase. We expect initial data from our Phase 2 gout study in H2 2027. Across the broader pipeline, we are pursuing a focused development strategy for MRT-2359 through MODeFIRe-1, evaluating its potential in combination with apalutamide in mCRPC patients with AR mutations. We have shown previously that degradation of GSPT1 dampens MYC signaling in CRPC, a pathway we believe is moving to center stage for new treatment options in CRPC. We look forward to a data update from this Phase 2 study in 2027, as well as a final data update from our completed Phase 1/2 study of MRT-2359 in combination with enzalutamide by year-end. Novartis's advancement of MRT-6160 (DDY391) into Phase 2 studies in Sjögren's disease and psoriatic arthritis expands the evaluation of VAV1 degradation across immune-mediated diseases and brings additional non-dilutive funding to Monte Rosa. With our balance sheet expected to support operations into 2029, we are well positioned to pursue these opportunities while maintaining a disciplined focus on generating clinical evidence and advancing our pipeline."

RECENT HIGHLIGHTS
MRT-8102, NEK7-directed MGD for inflammatory diseases driven by NEK7/NLRP3 and IL-1

- In October, Monte Rosa reported positive results from GFORCE-1 (NCT07119125), a Phase 1 study of MRT-8102 in 108 obese subjects with elevated cardiovascular disease risk. Across all three dose levels, MRT-8102 achieved median NEK7 degradation of approximately 80% to 90%. MRT-8102 also resulted in substantial reductions of IL-1β as well as HMGB1, calprotectin, S100A12, and SAA, damage-associated molecular patterns (DAMPs) linked to pathogenic biology within atherosclerotic plaques and vessel walls. MRT-8102 was well tolerated, with no serious adverse events, adverse event rates similar to placebo, and no evidence of increased infection risk.
- With dose selection informed by the GFORCE-1 data, Monte Rosa plans to initiate three Phase 2 studies of MRT-8102:

    - GEMINI-1, a Phase 2 study in patients with gout, is expected to initiate in Q4 2026. The study will evaluate prevention of flare recurrence following management of acute flares, with initial data expected in H2 2027.
    - GFORCE-2, a focused Phase 2b study in patients with stable coronary artery disease and residual inflammation, is expected to initiate in H1 2027. The study is expected to evaluate imaging-based coronary artery plaque assessment, such as fat attenuation index (FAI), along with NLRP3 genetics and molecular drivers of local disease pathogenesis and systemic inflammation, to inform the design of an innovative and efficient Phase 3 study focused on the most disease-modifiable patient population.
    - GALAXY-1, a Phase 2 study in patients with moderate to severe hidradenitis suppurativa, is expected to initiate in H1 2027.
- Due to prioritization of the MRT-8102 Phase 2 study initiations, Investigational New Drug (IND) submission for the next-generation NEK7 MGD is now anticipated in 2027.

MRT-2359, GSPT1-directed MGD for mCRPC

- In August, Monte Rosa dosed the first patient in MODeFIRe-1 (NCT07745361), a Phase 2 study of MRT-2359 in combination with apalutamide in AR-mutant mCRPC patients who received prior treatment with a second-generation AR inhibitor. The study will enroll up to 25 patients, with MRT-2359 administered orally at 0.5 mg on a 21 days on, 7 days off schedule. Endpoints include PSA response, RECIST response, duration of response, radiographic progression-free survival, PSA progression-free survival, and safety. Monte Rosa has a clinical supply agreement with Johnson & Johnson to support the study.
- Enrollment in the initial Phase 1/2 study expansion arm, in patients with mCRPC, has been completed. A total of 6 patients with AR mutations were enrolled and treated with MRT-2359 in combination with enzalutamide. Monte Rosa plans to provide an update on this patient subset by the end of the year. Interim data were presented at the ASCO Genitourinary Cancers Symposium (ASCO GU) in February.

MRT-6160 (DDY391), VAV1-directed MGD for immune-mediated conditions

- In September, Monte Rosa announced achievement of a milestone associated with its collaborator Novartis initiating a global Phase 2a/b randomized, double-blind, placebo-controlled study (NCT07737743), evaluating the efficacy, safety, and tolerability of up to 52 weeks of treatment with MRT-6160 (DDY391) in participants with Sjögren's disease. The first patient visit triggered a $50 million milestone payment to Monte Rosa.
- In October, Monte Rosa announced achievement of an additional milestone associated with Novartis initiating a second Phase 2 study of MRT-6160 (DDY391) in participants with active moderate to severe psoriatic arthritis (PsA). The Phase 2a/b randomized, double-blind, placebo-controlled, multicenter study (NCT07801495) will evaluate the efficacy, safety, tolerability, and dose-response relationship of MRT-6160 (DDY391). The first patient visit triggered a $37.5 million milestone payment to Monte Rosa.
- The Sjögren's and PsA studies are the first two of several studies expected for MRT-6160 (DDY391). Under its global exclusive development and commercialization license agreement with Novartis, Monte Rosa is eligible for additional Phase 2 study initiation milestone payments.

CDK2 and Cyclin E1-directed MGD programs for solid tumors

- Monte Rosa expects to submit IND applications for its CDK2 and cyclin E1 (CCNE1)-directed MGD programs in 2027.

ANTICIPATED UPCOMING MILESTONES AND DEVELOPMENT PRIORITIES
Immunology and inflammation programs

- Initiate GEMINI-1 Phase 2 study of MRT-8102 in gout in Q4 2026, with initial data expected in H2 2027.
- Initiate GFORCE-2 Phase 2b study of MRT-8102 in stable coronary artery disease in H1 2027.
- Initiate GALAXY-1 Phase 2 study of MRT-8102 in moderate to severe hidradenitis suppurativa in H1 2027.
- Monte Rosa expects its collaborator, Novartis, to initiate additional Phase 2 studies of MRT-6160 (DDY391) in immune-mediated diseases.

Oncology programs

- Provide a clinical data update on the initial Phase 1/2 expansion arm exploring MRT-2359 in combination with enzalutamide in mCRPC by the end of 2026.
- Provide a clinical data update on the MODeFIRe-1 Phase 2 study of MRT-2359 in combination with apalutamide in mCRPC patients with AR mutations in 2027.
- Submit an IND application for a CDK2-directed MGD in 2027.
- Submit an IND application for a CCNE1-directed MGD in 2027.

THIRD QUARTER 2026 FINANCIAL RESULTS
Collaboration Revenue: Collaboration revenue for the third quarter of 2026 was $54.4 million, compared to $12.8 million for the third quarter of 2025. The increase was primarily driven by recognition of collaboration revenue from the $50.0 million milestone triggered by the initiation of the Novartis Phase 2 study of MRT-6160 (DDY391) in participants with Sjögren's disease. The $37.5

million milestone triggered by the initiation of the Novartis Phase 2 study of MRT-6160 (DDY391) in participants with psoriatic arthritis in October is not reflected in third quarter collaboration revenue as it was triggered after the end of the quarter. Collaboration revenue represents amounts earned from Monte Rosa's collaboration and license agreements with Roche and Novartis.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2026 were $45.4 million, compared to $36.7 million for the third quarter of 2025. The increase was primarily driven by increased spending on development and discovery programs. R&D expenses included non-cash stock-based compensation of $3.3 million for the third quarter of 2026, compared to $2.5 million in the same period in 2025.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2026 were $10.9 million, compared to $9.1 million for the third quarter of 2025. G&A expenses included non-cash stock-based compensation of $3.0 million for the third quarter of 2026, compared to $1.9 million in the same period in 2025.

Net Income (Loss): Net income for the third quarter of 2026 was $3.1 million, compared to a net loss of $27.1 million for the third quarter of 2025.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2026, were $582.6 million, compared to $626.0 million as of June 30, 2026. The decrease of $43.4 million was primarily due to operational use of cash. In September, Monte Rosa announced achievement of a $50 million milestone associated with the first patient visit of the Novartis Phase 2 study of MRT-6160 (DDY391) in participants with Sjögren's disease. In October, Monte Rosa announced achievement of a $37.5 million milestone associated with the first patient visit of the Novartis Phase 2 study of MRT-6160 (DDY391) in participants with active moderate to severe psoriatic arthritis. Cash receipts from these milestones are not reflected in the September 30th cash balance as the payments had not yet been received as of that date. Monte Rosa expects that its cash, cash equivalents, restricted cash, and marketable securities will support operations 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 about our QuEEN™ discovery engine and the broad potential applications of the platform and our 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 our 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 (DDY391), including the initiation of Phase 2 clinical studies in Sjögren's disease and psoriatic arthritis by our collaborator Novartis, our expectations regarding the milestone payments triggered by the initiation of such Phase 2 studies, additional Phase 2 study activations expected to evaluate the potential of MRT-6160 (DDY391) across immune-mediated diseases, our eligibility for additional Phase 2 study initiation milestone payments, (ii) the ongoing development of our NEK7-directed MGD, referred to as MRT-8102, including the positive results from the GFORCE-1 Phase 1 study and the clinical significance of the data observed, statements regarding the potential of MRT-8102 to normalize local and systemic pathologic drivers of ASCVD and to provide differentiated clinical impact across NEK7/NLRP3-driven inflammatory diseases, including compared with targeting individual downstream cytokines, our expectations to initiate multiple Phase 2 studies of MRT-8102, including the GEMINI-1 study in gout patients in Q4 2026 with initial data expected in H2 2027, the GFORCE-2 Phase 2b study in patients with stable coronary artery disease and residual inflammation in H1 2027, including use of coronary artery imaging, NLRP3 genetics and biomarkers to identify a disease-modifiable patient population and inform the design of a potential Phase 3 study, and the GALAXY-1 study in moderate to severe hidradenitis suppurativa patients in H1 2027, statements regarding dose selection informed by GFORCE-1 data for further development across various NLRP3-driven diseases, statements regarding the potential of MRT-8102 in gout, (iii) the ongoing development of a next-generation NEK7-directed MGD and expected IND submission in 2027, (iv) our ongoing clinical development of MRT-2359, including the initiation of the MODeFIRe-1 Phase 2 study of MRT-2359 in combination with apalutamide in mCRPC patients with AR mutations, with potential to expand the study into additional patient subsets, our plans to provide updated data from the initial Phase 1/2 study expansion arm in patients with

metastatic CRPC by the end of the year, statements regarding the clinical significance of the data observed and the potential of MRT-2359 to benefit patients with mCRPC with AR mutations, and our clinical supply agreement with Johnson & Johnson to support such trial, and (v) progress of our CDK2 and cyclin E1-directed MGD programs, including the timing of IND application submissions in 2027 for CDK2-directed and cyclin E1-directed MGDs, as well as statements related to the expected potential clinical benefit of any of our candidates, advancement and application of our platform, 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 ability to optimize collaborations with industry partners, statements about obligations under our collaboration agreements, expectations around the receipt of payments under such agreements and the future development and commercialization of various products, statements regarding regulatory filings, including the planned timing of such filings, and potential review by regulatory authorities, our use of capital, expenses and other financial results in the future, 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, as well as the risk that outcomes of preclinical studies may not be predictive of clinical trial results and the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials. 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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 45,180	$ 129,883
Marketable securities	532,546	247,221
Collaboration receivable	50,000	7,000
Other receivables	7,624	4,600
Prepaid expenses and other current assets	4,715	4,481
Total current assets	640,065	393,185
Property and equipment, net	28,632	25,986
Operating lease right-of-use assets	23,343	24,386
Restricted cash	4,918	4,954
Other long-term assets	767	148
Total assets	$ 697,725	$ 448,659
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,347	$ 3,550
Accrued expenses and other current liabilities	33,414	26,694
Current deferred revenue	21,098	29,571
Current portion of operating lease liability	4,187	4,397
Total current liabilities	62,046	64,212
Deferred revenue, net of current	102,261	111,332
Defined benefit plan liability	5,131	5,265
Operating lease liability, net of current	32,079	34,794
Total liabilities	201,517	215,603
Stockholders' equity		

Common stock, $0.0001 par value; 500,000,000 shares authorized, 85,431,211 and 65,543,723 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	9	7
Additional paid-in capital	1,064,442	714,090
Accumulated other comprehensive loss	(6,192)	(3,827)
Accumulated deficit	(562,051)	(477,214)
Total stockholders' equity	496,208	233,056
Total liabilities and stockholders' equity	$ 697,725	$ 448,659

Consolidated Statements of Income (Loss)
(in thousands)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2026	**2025**	**2026**	**2025**
Collaboration revenue	$ 54,366	$ 12,768	$ 67,544	$ 120,891
Operating expenses:				
Research and development	45,363	36,678	137,396	99,521
General and administrative	10,942	9,065	31,251	25,863
Total operating expenses	56,305	45,743	168,647	125,384
Loss from operations	(1,939)	(32,975)	(101,103)	(4,493)
Other income:				
Interest income	5,625	2,746	17,132	9,253
Foreign currency exchange gain (loss)	93	(29)	110	1,534
Gain on disposal of property and equipment	—	—	—	59
Total other income	5,718	2,717	17,242	10,846
Net income (loss) before income taxes	$ 3,779	$ (30,258)	$ (83,861)	$ 6,353
Income tax (provision) benefit	(716)	3,177	(976)	1,156
Net income (loss)	$ 3,063	$ (27,081)	$ (84,837)	$ 7,509

Investors
Andrew Funderburk
ir@monterosatx.com

Media
Cory Tromblee, Scient PR
media@monterosatx.com