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

5.8.2025

VAV1-directed MRT-6160 program advancing toward multiple Phase 2 studies, enabled by Phase 1 SAD/MAD study data supporting broad potential application in immune-mediated diseases

MRT-2359 Phase 1/2 study data demonstrate encouraging signals of clinical response in heavily pretreated castration-resistant prostate cancer patients resistant to AR therapy; additional results expected in H2 2025

MRT-8102, a NEK7-directed molecular glue degrader targeting diseases driven by IL-1β and the NLRP3 inflammasome, on track for IND filing in H1 2025

Cyclin E1 (CCNE1) and CDK2-directed MGD programs for the treatment of CCNE1-driven solid tumors and ER+ breast cancer advancing toward the clinic; IND submission anticipated in 2026

Strong cash position expected to fund operations into 2028 through multiple anticipated proof-of-concept clinical readouts

BOSTON, May 08, 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 first quarter ended March 31, 2025.

“We’ve made significant progress across our entire portfolio in the development of our only-in-class and first-in-class molecular glue degrader therapeutics, targeting diseases poorly addressed by conventional pharmaceutical approaches,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “As highlighted in our recent pipeline update, our MRT-6160 Phase 1 study results support the broad potential application of this molecule as a novel treatment approach for immune-mediated diseases, and we are working diligently to advance the program into Phase 2 studies alongside our collaborators at Novartis. For our GSPT1 program, based on encouraging preliminary data from our ongoing Phase 1/2 study of MRT-2359 in MYC-driven solid tumors, we are focused on castration-resistant prostate cancer, an exciting opportunity in a population with widespread c-MYC expression. Study enrollment is ongoing, and we expect to report additional clinical data in H2 2025. Lastly, we continue to make excellent progress with our earlier stage programs. Our NEK7 program, targeting inflammatory diseases driven by IL-1β and the NLRP3 inflammasome, is on track, and we plan to file an IND submission for MRT-8102 in the first half of this year. Recent preclinical data for our CDK2-directed MGD highlight the substantially greater tumor regression achieved with our MGD combined with standard of care therapies compared to standard of care alone. We look forward to an IND submission for our CDK2 and/or CCNE1 cell cycle programs next year.”

RECENT HIGHLIGHTS

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

- In March 2025, Monte Rosa announced clinical results from its MRT-6160 Phase 1, single ascending dose / multiple ascending dose (SAD/MAD) study in healthy volunteers (clinicaltrials.gov identifier NCT06597799). The results support a clear path into anticipated Phase 2 studies and broad potential applications in multiple immune-mediated diseases. Further development of MRT-6160 toward Phase 2 studies is ongoing, in collaboration with Novartis.
- Monte Rosa has a global exclusive development and commercialization license agreement with Novartis to advance VAV1 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. 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.

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

- In March 2025, Monte Rosa provided updated clinical results in evaluating the safety, pharmacodynamics, and clinical activity of MRT-2359 in various tumor types. The Company has determined castration-resistant prostate cancer (CRPC) to be the primary MRT-2359 development focus. The Company continues to enroll and evaluate patients with CRPC, with the potential to expand enrollment to 20-30 patients if a positive efficacy signal continues to be observed, and expects to present additional results in H2 2025. Monte Rosa also continues to enroll and evaluate patients with HR+ breast cancer and expects to present additional results for this cohort in H2 2025.

NEK7-directed MGDs for inflammatory and CNS diseases driven by IL-1β and the NLRP3 inflammasome

- Monte Rosa has successfully completed GLP tox studies for MRT-8102, a first-in-class, NEK7-directed MGD for the treatment of inflammatory diseases driven by interleukin-1β (IL-1β) and the NLRP3 inflammasome, supporting a considerable safety margin. The Company is on track to submit an IND application for MRT-8102 in H1 2025 and plans to initiate Phase 1 healthy volunteer and proof-of-concept studies in individuals with high levels of C-reactive protein (CRP) and in cardio-immunology indications. The Company continues to evaluate future Phase 2 proof-of-concept studies in gout, pseudogout (calcium pyrophosphate deposition disease), and osteoarthritis.

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

- In April 2025, Monte Rosa presented preclinical data on the potential of its highly selective CDK2-directed molecular glue degrader, MRT-51443, to treat HR-positive/HER2-negative breast cancer at the American Association for Cancer Research (AACR) Annual Meeting 2025. MRT-51443 demonstrated superior anti-tumor activity in HR-positive/HER2-negative breast cancer models when combined with CDK4/6 inhibition and anti-estrogen therapy as compared to the standard-of-care combination of CDK4/6 inhibition and anti-estrogen therapy. Results also showed that MRT-51443 displayed superior selectivity compared to clinical-stage CDK2 inhibitors.

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

- Monte Rosa is advancing novel discovery programs for immunology and inflammation targets that the Company believes have the potential for highly differentiated, oral MGDs degrading undruggable targets in critical I&I pathways. These may include programs with the potential to improve upon the clinical profile of cell therapies, such as CAR-T, or biologics, such as FcRn inhibitors.

ANTICIPATED UPCOMING MILESTONES AND DEVELOPMENT PRIORITIES

- Continue advancement of MRT-6160 toward Phase 2 initiation, in collaboration with Novartis.
- Share additional MRT-2359 Phase 1/2 study data in CRPC patients resistant to androgen receptor (AR) therapy and in patients with HR+ breast cancer in H2 2025.
- Submit an IND application for MRT-8102 in H1 2025.
- Submit an IND application for the second-generation NEK7-directed MGD with enhanced CNS penetration in 2026.
- Submit an IND application for a CDK2 and/or cyclin E1-directed MGD in 2026.

FIRST QUARTER 2025 FINANCIAL RESULTS

Collaboration revenue: Collaboration revenue for the first quarter of 2025 was $84.9 million and $1.1 million for the quarter ended March 31, 2024. Collaboration revenue represents amounts earned from our collaboration and license agreements with Roche and Novartis, primarily revenue recognized from the Novartis $150 million upfront payment in the fourth quarter of 2024 based on progress made on our performance obligations defined in the Novartis License Agreement.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2025 were $32.2 million, compared to $27.0 million for the first quarter of 2024. These increases were driven by the successful achievement of key milestones in our R&D organization, including the continuation of the MRT-2359 clinical study, the progression and growth of our preclinical pipeline, including research performed in connection with our collaboration with Roche, the advancement of MRT-6160 to enter the clinic, and the continued development of the Company's QuEEN™ discovery engine. Approximately $1.0 million included in R&D expenses are to be reimbursed pursuant to our license agreement with Novartis. Non-cash stock-based compensation constituted $3.1 million of R&D expenses for Q1 2025, compared to $2.7 million in the same period in 2024.

General and Administrative (G&A) Expenses: G&A expenses for the first quarter of 2025 were $8.7 million compared to $9.0 million for the first quarter of 2024. G&A expenses included non-cash stock-based compensation of $2.2 million for the first quarter of 2025, compared to $2.2 million in the same period in 2024.

Net Income (Loss): Net income for the first quarter of 2025 was $46.9 million, compared to a net loss of $32.0 million for the first quarter of 2024.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2025, were $331 million, compared to cash, cash equivalents, restricted cash, and marketable securities of $377 million as of December 31, 2024. The decrease of $46 million was primarily due to the operational use of cash and one-time payments not recorded in operating expenses, including $12.2 million of value-added tax (VAT) collected from Novartis in the fourth quarter of 2024 in connection with the Novartis $150 million upfront payment and remitted to the Swiss Federal Tax Administration in the first quarter of 2025.

Based on current cash, cash equivalents, restricted cash, marketable securities, the Company expects its cash and cash equivalents to be sufficient to fund planned operations and capital expenditures into 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-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 CRPC patients resistant to AR therapy, a patient group characterized by widespread expression of c-MYC, MRT-2359 demonstrated encouraging early signals of clinical response.

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 driven by IL-1β and the NLRP3 inflammasome. 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.

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. 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 MGDs, which spans autoimmune and inflammatory diseases, oncology, and beyond. Monte Rosa has a global license agreement with Novartis to advance VAV1-directed molecular glue degraders and 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 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 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) our ongoing clinical development of MRT-2359, statements relating our ability to continue and expand the enrollment of patients with CRPC and HR+ breast cancer, statements regarding our belief that MRT-2359 Phase 1/2 study data demonstrates encouraging signals of clinical response in highly pretreated castration-resistant prostate cancer patients resistant to AR therapy and statements regarding the timing for data readouts in the second half of 2025, (ii) 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, (iii) the ongoing development and progress of our NEK7-directed MGD, referred to as MRT-8102, including our expectations to submit an IND to the FDA in the first half of 2025, and our statements around our plans to initiate Phase 1 healthy volunteer and proof-of-concept studies in individuals with high levels of CRP and cardio-immunology indications, as well as the Company's plans to evaluate future Phase 2 proof-of-concept studies in gout, pseudogout (calcium pyrophosphate deposition disease), and osteoarthritis, (iv) the ongoing development of a second-generation NEK7-directed MGD optimized for CNS penetration and our statements around expected IND submission in 2026, (v) statements around the progress of both our CDK2 and cyclin E1-directed

MGD programs, including statements around timing of submission of IND applications for such programs in 2026 and statements related to superior anti-tumor activity in vitro in HR+/HER2- breast cancer models when combined with CDK4/6 inhibition and anti-estrogen therapy as compared to the standard-of-care combination of CDK4/6 inhibition and anti-estrogen therapy, as well as statements related to superior selectivity compared to clinical-stage CDK2 inhibitors, 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 into 2028, 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, 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.

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

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 78,530	$ 224,254
Marketable securities	247,544	147,895
Other receivables	1,408	173
Prepaid expenses and other current assets	4,798	5,118
Total current assets	332,280	377,440
Property and equipment, net	29,336	29,483
Operating lease right-of-use assets	26,263	26,831
Restricted cash	4,880	4,863
Other long-term assets	440	115
Total assets	$ 393,199	$ 438,732
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,489	$ 17,215
Accrued expenses and other current liabilities	16,287	18,785
Current deferred revenue	32,575	117,232
Current portion of operating lease liability	3,865	3,714
Total current liabilities	59,216	156,946
Deferred revenue, net of current	16,863	16,147
Defined benefit plan liability	3,961	3,702
Operating lease liability	37,999	39,001
Total liabilities	118,039	215,796
Commitments and contingencies		
Stockholders' equity		

Common stock, $0.0001 par value; 500,000,000 shares authorized, 61,509,821 and 61,507,446 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	6	6
Additional paid-in capital	670,186	664,874
Accumulated other comprehensive loss	(3,329)	(3,356)
Accumulated deficit	(391,703)	(438,588)
Total stockholders' equity	275,160	222,936
Total liabilities and stockholders' equity	$ 393,199	$ 438,732

Consolidated Statement of Operations
(in thousands)
(unaudited)

	Three months ended March 31,	
	2025	**2024**
Collaboration revenue	$ 84,929	$ 1,064
Operating expenses:		
Research and development	32,190	$ 27,026
General and administrative	8,703	8,985
Total operating expenses	40,893	36,011
Income (loss) from operations	44,036	(34,947)
Other income:		
Interest income, net	3,439	2,442
Foreign currency exchange gain, net	173	620
Gain on disposal of fixed assets	59	—
Total other income	3,671	3,062
Net income (loss)	$ 47,707	$ (31,885)
Provision for income taxes	(822)	(83)
Net Income (loss)	$ 46,885	$ (31,968)

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