Molecular Partners Reports Highlights from Q4 2024 and Key Financials for Full Year 2024

March 6, 2025

- DLL3 targeting Radio-DARPin MP0712 to enter first-in-human study in 2025, pending regulatory clearance
- Strategic partnership with Orano Med on Radio-DARPins now expanded to ten programs
- MP0533 Phase 1/2a clinical data show improved response rate and depth in ongoing cohort, additional dosing optimization planned; data expected throughout 2025
- Strong financial position with CHF 149 million in cash, cash equivalents and short-term deposits at end of 2024, expected to support operations well into 2027
- Conference call to be held on Friday March 7, 2025 at 2.00 pm CET (8.00 am EST)

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., March 06, 2025 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR** Molecular Partners AG (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin therapeutics ("Molecular Partners" or the "Company"), today announced its corporate highlights and audited financial results for the full year 2024, as well as the publication of its 2024 Annual Report.

“Molecular Partners has made significant progress through 2024, setting us up for a number of key value inflection points. The potential of our Radio-DARPins is now well recognized in the field. In addition, we are advancing our next-generation immuno-oncology programs, including multispecific and Switch-DARPin T cell engagers”, said Patrick Amstutz, Ph.D., Chief Executive Officer of Molecular Partners.

"Our strategic Radio-DARPin partnership with Orano Med, expanded in January, is progressing well, and we named MSLN as our second RDT program for development. We anticipate submitting an IND application for MP0712 targeting DLL3 in H1 2025, with the start of first-in-human study and initial clinical data expected by year end. In our Phase 1/2a AML trial with MP0533, we expect data on the amended dosing scheme in 2025, and we plan to present further pre-clinical data on the CD3 Switch-DARPin at AACR in Q2 2025. We have a solid financial foundation, which provides funding through these value inflection points in 2025 and beyond."

Research & Development Highlights

MP0712 & Radio-DARPin Pipeline

The Investigational New Drug (IND) application for MP0712, a ^{212}Pb Radio-DARPin therapy (RDT) candidate targeting the tumor-associated protein delta-like ligand 3 (DLL3) and co-developed with Orano Med, is in preparation. Dialogue with the U.S. Food and Drug Administration (FDA) is ongoing, and Molecular Partners and Orano Med anticipate submitting the IND application for MP0712 in H1 2025, with the first-in-human study to start following regulatory clearance.

The IND submission is being built, in part, on strong MP0712 preclinical results, including new in vivo data presented at the European Association of Nuclear Medicine (EANM) Congress in October 2024 and the European Targeted Radiopharmaceuticals (TRP) Summit in December 2024. MP0712 demonstrated high affinity and specificity for DLL3, a highly relevant target for radiopharmaceutical therapy. DLL3 has been shown to have homogeneous expression in tumors of patients with small cell lung cancer (present in >85% of patients), and expression in healthy tissues is low.

The second RDT program co-developed with Orano Med targets mesothelin (MSLN), which is overexpressed across several cancers with high unmet need, such as ovarian cancer, and largely absent from healthy tissues. The development of therapeutics against MSLN has been hampered by high shedding of MSLN, leading to high levels of soluble MSLN. Leveraging the unique DARPin properties, Molecular Partners has developed Radio-DARPins able to selectively bind to the membrane-bound form of MSLN while not recognizing shed MSLN. Initial preclinical data for the MSLN program will be presented at the Annual Meeting of the American Association of Cancer Research (AACR) in Q2 2025.

Molecular Partners has leveraged the intrinsic properties of DARPins, such as small size, high affinity and specificity, to develop Radio-DARPins as ideal vector candidates for radiopharmaceutical therapeutics and to create a Radio-DARPin platform amenable to a broad range of tumor targets. Historically, small protein-based vectors faced challenges with kidney accumulation and toxicity, as well as suboptimal tumor uptake. Molecular Partners’ RDT platform addresses these limitations with the company’s half-life extension technologies and surface engineering approaches, while preserving the advantages of the small protein format.

Global Partnership with Orano Med to Develop ^{212}Pb-labeled Targeted Radiotherapeutics

In January 2024, Molecular Partners entered into a strategic collaboration with Orano Med to co-develop ^{212}Pb-based RDTs. The partnership combines Molecular Partners' leadership in DARPins with Orano Med’s leading expertise and unique capabilities in ^{212}Pb-based Targeted Alpha Therapy (TAT) preclinical and clinical development. In January 2025, the two companies further expanded their agreement to co-develop up to ten radiotherapy programs. Molecular Partners holds commercialization rights to MP0712, which is the most advanced program, and to the MSLN RDT program. In addition to its world class expertise and capabilities in the development of TAT with ^{212}Pb, Orano Med will also ensure the production of the ^{212}Pb-based Radio-DARPins for clinical trials and commercialization. Orano Med possesses virtually unlimited raw starting material for ^{212}Pb production and has established robust and independent supply and manufacturing capabilities required for the seamless delivery of TAT to clinical sites internationally.

In addition to the above updates, Molecular Partners continued to progress its RDT portfolio of projects in partnership with Novartis in 2024. As per contract terms, the research collaboration comes to a close in March 2025.

“We would like to thank Novartis for this groundbreaking research collaboration which enabled us to launch our activities in the field of targeted radiopharmaceuticals. We developed know-how, attracted a strong team of experts and evolved our Radio-DARPin platform. As it stands today, we are not planning to integrate these programs into our pipeline, while we are moving our first Radio-DARPin candidate MP0712, targeting DLL3, to the clinic this year”, said Patrick Amstutz.

MP0533 (multispecific T cell engager)

MP0533 is currently being evaluated in a Phase 1/2a clinical trial for relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome/AML (ClinicalTrials.gov: NCT05673057). Dose escalation in cohorts 1–7 showed an acceptable safety profile and initial activity, yet with unsustained responses (four responders reported and encouraging blast reductions across additional patients), as presented in December 2024 at the American Society of Hematology (ASH) meeting.

In the ongoing cohort 8, an additional dosing timepoint was introduced to allow steeper step-up and more frequent dosing to reach the MP0533 target dose faster. Initial data of this cohort indicate increased rates and depth of responses, with three out of eight evaluable patients demonstrating responses to-date (data cutoff 16 December 2024).

The study protocol is being amended to improve the exposure profile of MP0533 based on the learnings from the dose escalation. The amended protocol foresees, pending regulatory approval, further dose densification and premedication to mitigate loss of exposure for cohorts 9–10, with the objective to further increase the rate, depth and duration of responses observed in cohort 8. Data on the amended dosing scheme are expected in 2025.

MP0533 is a novel tetraspecific T cell-engaging DARPin which simultaneously targets the three tumor-associated antigens (TAAs) CD33, CD123, and CD70, as well as CD3 on T cells. The mechanism of action of MP0533 is designed to preferentially kill AML cells that express at least two of the three TAAs, while sparing healthy cells, which express only one or none of these TAAs. The immune activation against the malignant cells is achieved through CD3-mediated T cell engagement.

Switch-DARPin Platform (next-generation immune cell engagers)

By employing a multi-specific Switch-DARPin, Molecular Partners aims to increase the safety and potency of T cell engagers (TCEs). Preclinical proof-of-concept in a solid tumor model for a novel CD3 Switch-DARPin TCE was presented at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2024. The presented data provide further validation of Switch-DARPins and show that conditional T-cell activation with potent co-stimulation in solid tumors, but not in healthy tissues, is feasible. Molecular Partners will present further pre-clinical data on the CD3 Switch-DARPin at the AACR Annual Meeting in Q2 2025.

Molecular Partners’ first Switch-DARPin program, MP0621, is designed to induce killing of hematopoietic stem cells (HSCs) as a next-generation conditioning regimen for HSC transplantation. Pre-clinical proof-of-mechanism data were presented at the Annual Meetings of the European Hematology Association (EHA) and ASH in June and December 2024, respectively. As Molecular Partners’ portfolio strategy prioritizes therapeutic candidates for oncology, MP0621 is being evaluated for partnering.

Molecular Partners’ Switch-DARPin platform provides a logic-gated “on/off” function (the “Switch”) to multispecific DARPin candidates which leads to immune activation only in the presence of defined antigens and thereby enables conditional, tumor-localized next-generation immune cell engagers.

MP0317 (localized agonist)

Molecular Partners presented comprehensive biomarker analyses from the completed Phase 1 dose escalation trial of the localized CD40 agonist MP0317 in solid tumors at SITC in November 2024. MP0317 is designed to activate immune cells specifically within the tumor microenvironment by anchoring to fibroblast activation protein (FAP), which is expressed in high amounts in the stroma of various solid tumors. The Company believes this tumor-localized approach has the potential to deliver greater efficacy with fewer side effects compared to systemic CD40-targeting therapies.

Molecular Partners is in discussion with leading academic centers regarding potential investigator-initiated trials of MP0317 in 2025, in combination with immune checkpoint inhibitors and additional standard of care.

Corporate Governance & Leadership Highlights

In August 2024, Philippe Legenne, M.D., MBA was appointed Chief Medical Officer. Philippe brings significant and relevant clinical experience, having joined Molecular Partners in 2020, prior to which he led the oncology and biosimilar medical team for Amgen in the European Union, as well as senior roles at Novartis, GSK, and Janssen.

In February 2024 a putative class action complaint against Molecular Partners, its directors, and certain of its executive officers, originally filed in July 2022 in the U.S. District Court for the Southern District of New York, was dismissed in the Company’s favor, and the case was ordered closed.

2024 Financial Highlights

In October 2024, Molecular Partners raised approximately $20 million from both existing and new investors, such as HBM Partners, a leading healthcare investor based in Switzerland. The proceeds are being used to finance the development and expansion of Molecular Partners' radiopharmaceutical pipeline and platform (Radio-DARPin Therapeutics) and for working capital and other general corporate purposes.

In the financial year ended December 31, 2024, Molecular Partners recognized total revenues and other income of CHF 5.0 million (2023: CHF 7.0 million) and incurred total operating expenses of CHF 66.2 million (2023: CHF 68.1 million). This led to an operating loss of CHF 61.2 million for 2024 (2023: Operating loss of CHF 61.1 million). The net financial gain recorded in 2024 was CHF 7.2 million, compared to a net financial loss of CHF 0.9 million in 2023. This resulted in a 2024 net loss of CHF 54.0 million (2023: Net loss of CHF 62.0 million).

The net cash used in operating activities in 2024 was CHF 59.2 million (2023: Net cash used in operating activities CHF 59.0 million). Including short-term time deposits, the cash and cash equivalents position decreased by CHF 37.5 million as compared to year-end 2023, to CHF 149.4 million

as of December 31, 2024 (December 31, 2023: CHF 186.9 million). Total shareholders' equity stood at CHF 141.6 million as of December 31, 2024, a decrease of CHF 34.8 million (December 31, 2023: CHF 176.4 million).

The Company's cash and cash equivalents and short-term time deposits were CHF 149.4 million as of December 31, 2024, and based on current operating assumptions, will be sufficient to fund its operating expenses and capital expenditure requirements well into 2027.

The Company's balance sheet remained debt-free as of December 31, 2024. As of December 31, 2024, the Company employed 158.5 FTE (full-time equivalents), down 5% year-over-year. About 84% of the employees are employed in R&D-related functions.

Key figures as of December 31, 2024

Key Financials (CHF million, except per share, FTE data)	FY 2024	FY 2023	Change
Total revenues and other income	**5.0**	**7.0**	**(2.0)**
R&D expenses	(48.6)	(48.7)	0.1
SG&A expenses	(17.6)	(19.4)	1.8
Total operating expenses (incl depr. & amort.)	**(66.2)**	**(68.1)**	**1.9**
Operating result	**(61.2)**	**(61.1)**	**(0.1)**
Net finance result	7.2	(0.9)	8.1
Net result	**(54.0)**	**(62.0)**	**8.0**
Basic net result per share (in CHF)	(1.59)	(1.89)	0.30
Net cash (used in) from operating activities	(59.2)	(59.0)	(0.2)
Cash & cash equivalents (incl. short-term time deposits)	**149.4**	**186.9**	**(37.5)**
Total shareholders' equity	141.6	176.4	(34.8)
Number of total FTE	**158.5**	**167.5**	**(9.0)**

Financial outlook 2025

For the full year 2025, at constant exchange rates, the Company expects total operating expenses of CHF 55-65 million, of which around CHF 7 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation.

Documentation

This press release, the Company's Annual Report on Form 20-F for the year ended December 31, 2024 to be filed with the U.S. Securities and Exchange Commission (SEC), and the Company's annual report 2024 will be made available through www.molecularpartners.com under the investor section after 10.00 pm CET (4.00 pm EST) on March 6, 2025.

Full Year 2024 Conference Call & Audio Webcast

Molecular Partners will hold a conference call and audio webcast on March 7, 2025 at 2.00 pm CET (8.00 am EST).

To register for the full year 2024 conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

Participant Dial In (Toll Free):	1-844-763-8274
Participant International Dial In:	1-412-717-9224
Switzerland Toll Free:	044-575-0267

Participants in the conference call will have the opportunity to ask questions after the presentation.

A replay will be made available on the Company's website under the investor section. The replay will be available for 90 days following the presentation.

Financial calendar

April 16, 2025	Annual General Meeting
May 15, 2025	Interim Management Statement Q1 2025
August 25, 2025	Half-year results 2025 (unaudited)
October 30, 2025	Interim Management Statement Q3 2025

The latest timing of the above events can always be viewed on the investor section of the website.

About DARPin Therapeutics
DARPin (Designed Ankyrin Repeat Protein) therapeutics are a new class of custom-built protein drugs based on natural binding proteins that open new dimensions of multi-functionality and multi-target specificity in drug design. The flexible architecture, intrinsic potential for high affinity and specificity, small size and high stability of DARPins offer benefits to drug design over other currently available protein-based therapeutics. DARPin candidates can be radically simple, with a single DARPin unit acting as the delivery vector to a specific target; or multispecific, with the possibility of engaging more than five targets, and combining multiple and conditional functionalities in a unique DARPin drug candidate. The DARPin platform is designed to be a rapid and cost-effective drug discovery engine, producing drug candidates with optimized properties and high production yields. DARPin therapeutics have been clinically validated across several therapeutic areas and developed through to the registrational stage.

About Molecular Partners

Molecular Partners AG (SIX: MOLN, NASDAQ: MOLN) is a clinical-stage biotech company pioneering the design and development of DARPin therapeutics for medical challenges other drug modalities cannot readily address. The Company has programs in various stages of pre-clinical and clinical development, with oncology as its main focus. Molecular Partners leverages the advantages of DARPins to provide unique solutions to patients through its proprietary programs as well as through partnerships with leading pharmaceutical companies. Molecular Partners was founded in 2004 and has offices in both Zurich, Switzerland and Concord, MA, USA. For more information, visit www.molecularpartners.com and find us on LinkedIn and Twitter / X @MolecularPrtnrs

For further details, please contact:
Seth Lewis, SVP Investor Relations & Strategy
Concord, Massachusetts, U.S.
seth.lewis@molecularpartners.com
Tel: +1 781 420 2361

Laura Jeanbart, PhD, Head of Portfolio Management & Communications
Zurich-Schlieren, Switzerland
laura.jeanbart@molecularpartners.com
Tel: +41 44 575 19 35

Cautionary Note Regarding Forward-Looking Statements
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, as amended, including without limitation: implied and express statements regarding the clinical development of Molecular Partners' current or future product candidates; expectations regarding timing for reporting data from ongoing clinical trials or the initiation of future clinical trials; the potential therapeutic and clinical benefits of Molecular Partners' product candidates and its RDT and Switch-DARPin platforms; the selection and development of future programs; Molecular Partners' collaboration with Orano Med including the benefits and results that may be achieved through the collaboration; and Molecular Partners' expected business and financial outlook, including anticipated expenses and cash utilization for 2025 and its expectation of its current cash runway and the expected use of proceeds from the October 2024 offering. These statements may be identified by words such as "aim", "anticipate", "expect", "guidance", "intend", "outlook", "plan", "potential", "will" and similar expressions, and are based on Molecular Partners' current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Some of the key factors that could cause actual results to differ from Molecular Partners' expectations include its plans to develop and potentially commercialize its product candidates; Molecular Partners' reliance on third party partners and collaborators over which it may not always have full control; Molecular Partners' ongoing and planned clinical trials and preclinical studies for its product candidates, including the timing of such trials and studies; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future clinical trials; the timing of and Molecular Partners' ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Molecular Partners' product candidates; the clinical utility and ability to achieve market acceptance of Molecular Partners' product candidates; the potential that Molecular Partners' product candidates may exhibit serious adverse, undesirable or unacceptable side effects; the impact of any health pandemic, macroeconomic factors and other global events on Molecular Partners' preclinical studies, clinical trials or operations, or the operations of third parties on which it relies; Molecular Partners' plans and development of any new indications for its product candidates; Molecular Partners' commercialization, marketing and manufacturing capabilities and strategy; Molecular Partners' intellectual property position; Molecular Partners' ability to identify and in-license additional product candidates; unanticipated factors in addition to the foregoing that may cause Molecular Partners' actual results to differ from its financial and business projections and guidance; and other risks and uncertainties set forth in Molecular Partners' Annual Report on Form 20-F for the year ended December 31, 2024 and other filings Molecular Partners makes with the SEC from time to time. These documents are available on the Investors page of Molecular Partners' website at www.molecularpartners.com. In addition, this press release contains information relating to interim data as of the relevant data cutoff date, results of which may differ from topline results that may be obtained in the future. Any forward-looking statements speak only as of the date of this press release and are based on information available to Molecular Partners as of the date of this release, and Molecular Partners assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.