0001171843-25-0002136-K MOLECULAR PARTNERS AG 2025011320250113171433171433171433 0 0001171843-25-000213 6-K 2 20250112 20250113 20250113 MOLECULAR PARTNERS AG 0001745114 2836 000000000 V8 1231 6-K 34 001-40488 25527058 WAGISTRASSE 14 Z?RICH-SCHLIEREN V8 8952 41 44 755 77 00 WAGISTRASSE 14 Z?RICH-SCHLIEREN V8 8952 6-K 1 f6k_011325.htm FORM 6-K Â UNITED STATESSECURITIES AND EXCHANGE COMMISSIONWashington, D.C. 20549Form 6-KREPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934For the month of January 2025Commission File Number: 001-40488Molecular Partners AG(Translation of registrant's name into English)Wagistrasse 148952 Zurich-SchlierenSwitzerland(Address of principal executive office)Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.Form 20-F [Â X] Â Â Â Â Â Form 40-F [Â Â]Â Â On January 12, 2025, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. (c) Exhibit 99.1. Press release dated January 12, 2025SIGNATURESPursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.Â Â Â Â Â Â Molecular Partners AGÂ Â Â Â Â Â (Registrant)Â Â Â Â Â Date: January 12, 2025Â Â Â Â Â /s/ PATRICK AMSTUTZÂ Â Â Â Â Â Patrick AmstutzÂ Â Chief Executive OfficerÂ Â EX-99.1 2 exh_991.htm PRESS RELEASE EdgarFilingEXHIBIT 99.1Molecular Partners Outlines Clinical Expansion Plans and Strengthens Radiopharma Strategic Focus for 2025 at 43rd Annual J.P. Morgan Healthcare Conference Radio-DARPin MP0712 against DLL3, in co-development with Orano Med, to enter first-in-human study in 2025Mesothelin named as second target in Radio-DARPin pipeline, program to be co-developed with Orano MedOrano Med partnership on Radio-DARPins now expanded to 10 programsMP0533 clinical data show improved response rate and depth in cohort 8 with steeper step-up and more frequent dosing; additional dose densification planned in cohort 9, updates expected in 2025CD3 Switch-DARPin research proof-of-concept of conditional T cell activation and CD2 co-stimulation shown in solid tumors, further data in Q2 2025 ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Jan. 12, 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 (â€œMolecular Partnersâ€ or the â€œCompanyâ€), today provided an update on its programs, development plans and guidance on key milestones expected in 2025, to be presented at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, California. "We are excited to enter 2025 with upcoming key value inflection points, on the Radio-DARPin side as well as Switch-DARPin and clinical T-cell engagers, to build on our achievements through 2024. Our recently expanded strategic partnership with Orano Med ensures us access to 212Pb, to arm our Radio-DARPins for up to 10 products. MP0712, our most advanced Radio-DARPin targetingÂ DLL3, is moving into clinical development in 2025. Further, we have selected Mesothelin as the secondÂ target in the Orano Med partnership, with unique DARPin binders that only bind to juxtamembrane Meso while not being inhibited by the shed target,â€ said Patrick Amstutz, Ph.D., CEO of Molecular Partners. Molecular Partners has further strengthened and expanded its agreement with Orano Med for co-development of up to ten 212Pb-based Radio-DARPins. Molecular Partners holds commercialization rights to MP0712, which is the most advanced program, as well as the second nominated Radio-DARPin candidate, which targets the membrane-proximal portion of cell surface glycoprotein Mesothelin (MSLN). Orano Med will ensure the production of the 212Pb-based Radio-DARPins for clinical trials and commercialization. Further details on this second candidate are scheduled to be unveiled at the Annual Meeting of the American Association of Cancer Research (AACR) in Q2 2025. Patrick Amstutz continued, â€œWe are equally excited that our work on the MP0533 candidate in R/R AML is starting to yield encouraging results. As we work to implement our previously discussed protocol amendments, we are already starting to see patients benefit from treatment in our ongoing cohort 8, where we introduced an additional dosing timepoint early on. These preliminary data provide us with reassurance that our strategy to further densify early dosing has merit and could enable more patients to benefit longer from MP0533.â€ Cash and Cash Equivalents:As of Dec 31 2024, Molecular Partners reports cash and cash equivalents of CHF 149 M (unaudited) and will provide full YE financial results on March 6, 2025. Key current program status updates include: MP0712 & Radio-DARPin pipeline The Investigational New Drug (IND) application for MP0712, a 212Pb Radio-DARPin candidate against the tumor-associated protein delta-like ligand 3 (DLL3), 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 Congress in October 2024 and the European Targeted Radiopharmaceuticals Summit in December 2024. MP0712 demonstrated high affinity and specificity for DLL3, which is a highly relevant target for radiopharmaceutical therapy. DLL3 has been shown to have homogeneous expression in tumors of patients with small cell lung cancer, and expression in healthy tissues is low. The second Radio-DARPin program co-developed with Orano Med targets 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. Leveraging the unique DARPin properties, Molecular Partners has developed Radio-DARPins able to selectively bind to the membrane-proximal portion of MSLN present on cells and are therefore not impacted by shed MSLN. In addition to the above updates, Molecular Partners continues to progress its Radio-DARPin Therapy (RDT) portfolio of projects in partnership with Novartis and is evaluating additional targets for RDT programs. 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 cohort 1â€“7 showed an acceptable safety profile and initial activity yet unsustained responses (four responders reported and encouraging blast reductions across additional patients), as presented in December 2024 at the American Society of Hematology meeting. In the currently ongoing cohort 8, in which an additional early dosing timepoint was introduced to allow steeper and more frequent dosing to reach the MP0533 target dose faster, increased rates and depth of responses are being observed, with three out of the first eight evaluable patients demonstrating responses to-date (data cutoff 16 December 2024). Molecular Partners has submitted an amendment to the study protocol to improve the exposure profile of MP0533 and to further deepen and expand responses being 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 targets. The immune activation against the malignant cells is achieved through CD3-mediated T cell engagement. Switch-DARPin Platform (next-generation

immune cell engagers) Preclinical proof-of-concept in a solid tumor model for the novel T cell engager Switch-DARPin was presented at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November. The presented data provide further validation of Switch-DARPins showing that conditional Tcell activation with potent co-stimulation in solid tumors, but not in healthy tissues, is feasible. Specifically, the CD3 Switch-DARPin molecule was shown to effectively induce potent tumor regression in vivo. Reduced cytokine release was observed in healthy tissues compared to tumor tissue. Cytokine release syndrome (CRS) is a significant toxicity event that has been observed with many T cell engagers in the clinic. As such, masking CD3 may prevent T cell activation in the absence of tumor antigens and allow for â€œsilentâ€ T cell engagers outside of tumors, thereby reducing the risk of CRS and providing a better safety profile to T cell engagers. In addition, co-engagement of CD2 led to sustained T cell activation and cytotoxic capacity, thereby enabling the development of potent T cell engagers with improved therapeutic window. Molecular Partners plans to present further in vivo data on the CD3 Switch-DARPin at the AACR Annual Meeting in Q2 2025. MP0317 (localized agonist) Molecular Partners presented comprehensive biomarker analyses from the completed Phase 1 clinical trial of the 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. 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 combination trials of MP0317 in 2025, in combination with immune checkpoint inhibitors and additional standard of care.J.P. Morgan Presentation Details: Presenter: Molecular Partners CEO Patrick AmstutzTime: January 15, 2025, at 9:00 AM PST (6:00 PM CET)Location: Westin St. Francis, Elizabethan A Ballroom, San Francisco, CA A webcast will be accessible on the Molecular Partners website, under the Events tab. About Molecular Partners AGÂ 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 & StrategyConcord, Massachusetts, U.S.seth.lewis@molecularpartners.comTel: +1 781 420 2361 Laura Jeanbart, PhD, Head of Portfolio Management & Communications Zurich-Schlieren, Switzerlandlaura.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 Partnersâ€™ 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 Partnersâ€™ product candidates and its RDT and Switch-DARPin platforms; the selection and development of future programs; Molecular Partnersâ€™ collaboration with Orano Med including the benefits and results that may be achieved through the collaboration; and Molecular Partnersâ€™ expected business and financial outlook, including anticipated expenses and cash utilization for 2024 and its expectation of its current cash runway and the expected use of proceeds from the underwritten offering. These statements may be identified by words such as â€œaimâ€, â€œexpectâ€, â€œguidanceâ€, â€œintendâ€, â€œoutlookâ€, â€œplanâ€, â€œpotentialâ€, â€œwillâ€ and similar expressions, and are based on Molecular Partnersâ€™ 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 Partnersâ€™ expectations include its plans to develop and potentially commercialize its product candidates; Molecular Partnersâ€™ reliance on third party partners and collaborators over which it may not always have full control; Molecular Partnersâ€™ 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 Partnersâ€™ ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Molecular Partnersâ€™ product candidates; the clinical utility and ability to achieve market acceptance of Molecular Partnersâ€™ product candidates; the potential that Molecular Partnersâ€™ 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 Partnersâ€™ preclinical studies, clinical trials or operations, or the operations of third parties on which it relies; Molecular Partnersâ€™ plans and development of any new indications for its product candidates; Molecular Partnersâ€™ commercialization, marketing and manufacturing capabilities and strategy; Molecular Partnersâ€™ intellectual property position; Molecular Partnersâ€™ ability to identify and in-license additional product candidates; unanticipated factors in addition to the foregoing that may impact Molecular Partnersâ€™ financial and business projections and guidance; and other risks and uncertainties set forth in Molecular Partnersâ€™ Annual Report on Form 20-F for the year ended December 31, 2023 and other filings Molecular Partners makes with the SEC from time to time. These documents are available on the Investors page of Molecular Partnersâ€™ 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.