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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 6-K**

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**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

**For the month of December, 2024**

**Commission File Number: 001-36619**

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**Affimed N.V.**

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**Gottlieb-Daimler-Straße 2,  
68165 Mannheim  
Germany**  
(Address of principal executive offices)

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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       Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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## Affimed N.V.

Affimed N.V. (Nasdaq: AFMD) (“Affimed”, or the “Company”) today announced updated clinical data from the ongoing AFM24-102 trial of AFM24/atezolizumab combination therapy in heavily pretreated non-small cell lung cancer (“NSCLC”) patients.

### NSCLC *EGFR* Wild-type Cohort Update

**Patient population:** As of the November 14, 2024 data cut, there were 43 patients in the full analysis set (FAS) and 33 patients in the per protocol set (PPS), defined as having one post baseline scan according to RECIST. Reasons for non-evaluability were early symptomatic deterioration (6), non-related AEs (2), too early (2). Patients had a median of 2 prior lines of therapy (range: 1–7). All patients had received platinum-based combinations and PD(L) 1 targeting checkpoint inhibitors (CPIs), and two-thirds had received taxanes. Importantly, all but one patient discontinued their previous CPI because of progression.

**Safety:** The AFM24 and atezolizumab combination therapy was well tolerated with no unexpected safety findings. Infusion related reactions (IRRs) were the most common adverse event (AE) reported, in 54% of patients; IRRs were manageable, mostly present during the first infusion, and fully resolved. Elevations of alanine aminotransferase (ALT) and aspartate aminotransferase (AST), a known side effect of atezolizumab, were reported in 21% and 16% of patients respectively.

**Anti-tumor activity and durability (N=33, PPS):** The combination demonstrated an ORR of 21% (7 responses: 1 complete response (CR), 5 partial responses (PR) and 1 additional not yet confirmed PR), tumor shrinkage in 48% of patients (16/33 patients) and a DCR of 76%. In the 7 responders, 5 had never achieved an objective response on prior CPIs and only 2 patients had a PR on previous CPI containing treatment (both to a triplet of platinum, pemetrexed and CPI). The preliminary median PFS is 5.6 months, and 36% of patients are currently on treatment.

### NSCLC *EGFR* Mutant Cohort Update

**Patient population:** As of the November 14, 2024 data cut, 28 patients were in the FAS (reasons for non-evaluability at the cut-off were: ongoing with no scan yet 5, early deterioration 4, non-related AEs 2), with updated results presented for the first 17 patients in the PPS. All patients had received prior epidermal growth factor receptor (“EGFR”) specific TKI therapy, and 77% had received platinum-based chemotherapy.

**Anti-tumor activity and durability (N=17, PPS):** AFM24 combined with atezolizumab showed promising activity in refractory NSCLC *EGFR* mutant patients achieving an ORR of 24% (4 confirmed responses: 1 CR, 3 PRs), a DCR of 71% and tumor shrinkage in 41% of patients. With a median follow-up of 9 months, the median PFS was 5.6 months. Five (29%) patients are on treatment for over 10 months, demonstrating long term tumor control.

### Post-Hoc Exposure-Response Analysis

**Analysis process:** A post-hoc exposure-response analysis was conducted including NSCLC *EGFR*-wildtype and *EGFR* mutant subjects (n= 44) treated with 480 mg AFM24 in both the AFM24-101 monotherapy study or the AFM24-102 AFM24 combination with atezolizumab study. Low and high exposure groups were calculated using a median cut-point of patient’s mean trough values.

**Safety, anti-tumor activity and durability:** Baseline characteristics were balanced between the high and low exposure groups and there were no differences in body mass index or percentage of administered dose that would explain differences in exposure. The high exposure group showed an ORR of 46% and a PFS of 7.4. A sensitivity analysis using quartiles of exposure supported a clear relationship between exposure and outcome indicating that higher doses of AFM24 will likely result in improved efficacy. The PK profile of 720 mg AFM24 weekly, as tested successfully in the phase 1 trial and further pharmacokinetic modelling indicate that 720 mg will achieve exposure levels that are equal or above the plasma concentrations observed for the high exposure group.

**Cash runway into Q4 2025:** The Company is projected to end Q4 2024 with approximately €15 million and cash runway projected into Q4 2025.

This report on Form 6-K (this “Report”) shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-282978), Form S-8 (Registration Number 333-198812) and Form S-8 (Registration Number 333-270798) of Affimed N.V. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished and shall not be deemed filed or incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

## FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions. Forward-looking statements appear in a number of places throughout this release and include statements regarding the Company’s intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the potential of acimtamig (AFM13), AFM24, AFM28 and the Company’s other product candidates, the value of its ROCK<sup>®</sup> platform, its ongoing and planned preclinical development and clinical trials, its collaborations and development of its products in combination with other therapies, the timing of and its ability to make regulatory filings and obtain and maintain regulatory approvals for its product candidates, its intellectual property position, its collaboration activities, its ability to develop commercial functions, clinical trial data, its results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies, the industry in which it operates, the macroeconomic trends that may affect the industry or the Company, such as the instability in the banking sector experienced in the first quarter of 2023, impacts of the COVID-19 pandemic, the benefits to Affimed of orphan drug designation, the impact on its business by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties, such as the Russia-Ukraine conflict, the fact that the current clinical data of acimtamig in combination with NK cell therapy is based on acimtamig precomplexed with fresh allogeneic cord blood-derived NK cells from The University of Texas MD Anderson Cancer Center, as opposed to Artiva’s AB-101, and other uncertainties and factors described under the heading “Risk Factors” in Affimed’s filings with the SEC. Given these risks, uncertainties, and other factors, you should not place undue reliance on these forward-looking statements, and the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

**SIGNATURES**

Pursuant 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.

Date: December 17, 2024

**AFFIMED N.V.**

By: /s/ Shawn Leland

Name: Shawn Leland

Title: Chief Executive Officer

By: /s/ Denise Mueller

Name: Denise Mueller

Title: Chief Business Officer

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**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description of Exhibit</b>
99.1	Affirmed N.V. Press Release dated December 17, 2024.



## PRESS RELEASE

**Affimed Reports Positive Clinical Update on AFM24/Atezolizumab  
Combination Therapy in Non-Small Cell Lung Cancer (NSCLC)**

- In 33 heavily pretreated NSCLC *EGFR* wild-type (*EGFR*wt) patients the combination of AFM24 and atezolizumab shows an overall response rate (ORR) of 21% (6 confirmed responses, 1 response awaiting confirmatory scan) and a disease control rate (DCR) of 76%; tumor shrinkage was observed in 48% of patients; preliminary median progression free survival (PFS) is 5.6 months and 36% of patients remain on treatment
- In 17 heavily pretreated NSCLC *EGFR* mutant (*EGFR*mut) patients the combination shows an ORR of 24% and a DCR of 71%; tumor shrinkage was observed in 41% of patients; median PFS is 5.6 months and 5 patients (29%) are on treatment for over 10 months
- Both cohorts demonstrated a well-manageable side effect profile with no new safety signals identified
- A post hoc analysis demonstrated that patients who achieve higher exposure of AFM24 had significantly higher response rates and improved PFS and survival compared to patients with lower exposure
- Company to review results on a webcast today at 8:30 am EST / 14:30 CET

**MANNHEIM, Germany, December 17, 2024** – Affimed N.V. (Nasdaq: AFMD) (“Affimed”, or the “Company”), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, today announced updated clinical data from the ongoing AFM24-102 trial of AFM24/atezolizumab combination therapy in heavily pretreated NSCLC patients. Results continue to demonstrate meaningful clinical activity in both NSCLC *EGFR*wt and *EGFR*mut patients with good tolerability. In addition, the Company reported findings from a post-hoc exposure-response analysis in patients treated with 480 mg AFM24 showing higher AFM24 exposure is associated with significantly better response rates, improved PFS and overall survival (OS). Based on these data, the future development program for AFM24 will use a dose of 720 mg weekly, a dose that has already been successfully tested in the phase 1 study of AFM24 showing a manageable safety profile.

“With the compelling data from both *EGFR* wild-type and mutant cohorts, along with the exposure-response analysis we are unlocking the possibilities for the AFM24/atezolizumab combination in treating heavily pretreated NSCLC patients,” said Dr. Shawn Leland, PharmD, RPh, Chief Executive Officer of Affimed. “These findings highlight our opportunity to further refine and advance this treatment with a clear focus on patients who stand to benefit the most. We are excited about the path ahead and are committed to exploring innovative strategies to bring this promising therapy to those in need.”

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“Advanced-stage NSCLC remains one of the most challenging cancers to treat, and our findings bring new hope,” said Dr. Andreas Harstrick, MD, Chief Medical Officer of Affimed. “We see compelling efficacy results with the AFM24/atezolizumab combination in heavily pretreated NSCLC patients, independent from the mutational status. The results are remarkable as we achieve this with a purely immunotherapy-based approach in patients that are often not able or not willing to take additional toxic therapies. The insights in the relation of exposure and efficacy will allow us to further improve on the efficacy and provide a clear path forward as we strive to unlock new possibilities for *EGFR* NSCLC patients.”

## **About AFM24**

AFM24 is a tetravalent, bispecific ICE<sup>®</sup> that activates the innate immune system by binding to CD16A on innate immune cells and epidermal growth factor receptors (EGFR), a protein widely expressed on solid tumors, to kill cancer cells. Generated by Affimed's fit-for-purpose ROCK<sup>®</sup> platform, AFM24 represents a distinctive mechanism of action that uses EGFR as a docking site to engage innate immune cells for tumor cell killing through antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.

## **About Affimed N.V.**

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer by actualizing the untapped potential of the innate immune system. The Company's innate cell engagers (ICE<sup>®</sup>) enable a tumor-targeted approach to recognize and kill a range of hematologic and solid tumors. ICE<sup>®</sup> are generated on the Company's proprietary ROCK<sup>®</sup> platform which predictably generates customized molecules that leverage the power of innate immune cells to destroy tumor cells. A number of ICE<sup>®</sup> molecules are in clinical development, being studied as mono- or combination therapy. Headquartered in Mannheim, Germany, Affimed is led by an experienced team of biotechnology and pharmaceutical leaders united by the bold vision to stop cancer from ever derailing patients' lives. For more about the Company's people, pipeline and partners, please visit: [www.affimed.com](http://www.affimed.com).

## **Forward-Looking Statements**

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