UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

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

For the month of January, 2024

Commission File Number: 001-36619

Affimed N.V.

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

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):

Affimed N.V.

On January 8, 2024, Affimed N.V. (the "Company" or "Affimed") issued a press release titled "Affimed Provides Clinical Response Update on AFM24-102 Trial in EGFR-wildtype Non-Small Cell Lung Cancer" announcing an update on the clinical response data for the ongoing AFM24-102 phase 1/2a study in epidermal growth factor receptor ("EGFR")-wildtype ("wt") non-small cell lung cancer ("NSCLC").

As of January 4, 2024 the updated information on the 4 responses in the 15 patients treated in the EGFRwt NSCLC cohort, now show 1 confirmed complete response (CR), 2 confirmed partial responses (PR) and 1 unconfirmed PR awaiting confirmation. Initial data as presented on December 11, 2023, showed 1 confirmed PR as well as 1 unconfirmed CR, and 2 unconfirmed PRs. The patients enrolled in the Phase 1/2a AFM24-102 in the EGFRwt NSCLC cohort of the trial previously had a median of 2 prior lines of therapy, were heavily pretreated, and all patients had progressed on PD-[L]1 targeted therapy.

Based on the promising response data from the EGFRwt NSCLC cohort, Affimed will expand enrollment to 40 patients. Additionally, the Company reported that enrollment of the EGFR-mutant NSCLC cohort is ongoing. Data from both cohorts are expected in the first half of 2024.

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® platform, its ongoing and planned preclinical development and clinical trials, the restructuring plan, including the workforce reduction, dissolution of the research department and divestiture of AbCheck, 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 (AFM13) in combination with NK cell therapy is based on acimtamig (AFM13) precomplexed with fresh allogeneic cord blood-derived NK cells from The University of Texas MD Anderson Cancer Center, as opposed to Artiva's AlloNK® 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: January 8, 2024

AFFIMED N.V.

By: /s/ Denise Mueller

Name: Denise Mueller Title: Chief Business Officer

By: /s/ Andreas Harstrick

Name: Andreas Harstrick Title: Chief Medical Officer

Exhibit Description of Exhibit

99.1 Affimed N.V. Press Release dated January 8, 2024.



PRESS RELEASE

Affimed Provides Clinical Response Update on AFM24-102 Trial in EGFR-wildtype Non-Small Cell Lung Cancer

- Data update from AFM24-102 Phase 1/2a combination study includes 15 heavily pre-treated patients from the *EGFR*-wildtype (wt) non-small cell lung cancer (NSCLC) expansion cohort
- Follow-up shows three of the initially reported responses have now been confirmed (1 CR, 2 PR) and one still awaiting a confirmatory scan
- Study to be expanded to a total of 40 EGFRwt NSCLC patients
- Enrollment in the EGFR-mutant (mut) NSCLC cohort is ongoing
- Data from both the EGFRwt and EGFRmut cohorts expected in H1 2024

Mannheim, Germany, January 8, 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 provided an update on the clinical response data for the ongoing AFM24-102 phase 1/2a study in *EGFR*wt NSCLC.

As of January 4, 2024, updated information on the 4 responses in the 15 patients treated in the *EGFR*wt NSCLC cohort, now show 1 confirmed complete response (CR), 2 confirmed partial responses (PR) and 1 unconfirmed PR awaiting confirmation. Initial data as presented on December 11, 2023, showed 1 confirmed PR as well as 1 unconfirmed CR, and 2 unconfirmed PRs. The patients enrolled in the Phase 1/2a AFM24-102 in the *EGFR*wt NSCLC cohort of the trial previously had a median of 2 prior lines of therapy, were heavily pretreated, and all patients had progressed on PD-[L]1 targeted therapy.

Based on the promising response data from the *EGFR*wt NSCLC cohort, Affimed will expand enrollment to 40 patients. Additionally, the Company reported that enrollment of the *EGFR*mut NSCLC cohort is ongoing. Data from both cohorts are expected in H1 2024.

"We are encouraged by the responses in these patients that had all progressed on PD1 targeting therapy and made the strategic decision to expand this patient cohort," said Dr. Andreas Harstrick, CMO and interim Chief Executive Officer of Affimed. "There is a significant unmet need for these patients who have exhausted all previous lines of therapy and did not respond to any therapies, including PD-1/PD-L1 treatment. We look forward to sharing more updates in the first half of 2024."

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 proprietary ROCK[®] platform enables a tumor-targeted approach to recognize and kill a range of hematologic and solid tumors, enabling a broad pipeline of wholly-owned and partnered single agent and combination therapy programs. The ROCK[®] platform predictably generates customized innate cell engager (ICE[®]) molecules, which use patients' immune cells to destroy tumor cells. This innovative approach enabled Affimed to become the first company with a clinical-stage ICE[®]. Headquartered in Mannheim, Germany, Affimed is led by an experienced team of biotechnology and pharmaceutical leaders united by a bold vision to stop cancer from ever derailing patients' lives. For more about the Company's people, pipeline and partners, please visit: <u>www.affimed.com</u>.

About the AFM24-102 Phase 1/2a Study

AFM24-102 is a Phase 1/2a open-label, non-randomized, multicenter, dose escalation, and expansion study evaluating AFM24 in combination with atezolizumab in patients with selected EGFR-expressing advanced solid malignancies whose disease has progressed after treatment with previous anticancer therapies (NCT05109442).

About AFM24

AFM24 is a tetravalent, bispecific innate cell engager (ICE[®]) that activates the innate immune system by binding to CD16A on innate immune cells and EGFR, a protein widely expressed on solid tumors, to kill cancer cells. Generated by Affimed's fit-for-purpose ROCK[®] 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.

In addition to studying AMF24 in combination with the checkpoint inhibitor atezolizumab, Affimed is also evaluating options for a combination of AFM24 with an allogeneic off-the-shelf NK cell product that the Company expects to be well suited for heavily pretreated patient populations.

Forward-Looking Statement

This press release 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 AFM13, AFM24, AFM28 and the Company's other product candidates, the value of its ROCK® 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 AFM13 in combination with NK cell therapy is based on AFM13 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.

Investor Relations Contact

Alexander Fudukidis Director, Investor Relations E-Mail: <u>a.fudukidis@affimed.com</u> Tel.: +1 (917) 436-8102

Media Contact

Mary Beth Sandin Vice President, Marketing and Communications E-Mail: <u>m.sandin@affimed.com</u>