

---

---

**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 June, 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 June 1, 2024, Affimed N.V. (the “Company” or “Affimed”) issued a press release titled “Affimed Provides Follow-up Data of AFM24 plus Atezolizumab Showing Durable Responses in Heavily Pretreated NSCLC EGFR Wild-type Patients and Positive Initial Data from the NSCLC EGFR Mutant Cohort” announcing longer follow-up data from the epidermal growth factor receptor wild-type (“*EGFRwt*”) cohort and initial clinical efficacy data from the *EGFR* mutant (“*EGFRmut*”) cohort from the on-going AFM24-102 study in non-small cell lung cancer (“NSCLC”).

As of the updated data cutoff on May 13, 2024 for the 17 *EGFRwt* patients previously reported on, 15 patients were response-evaluable. Four confirmed objective responses were seen: 1 complete response (“CR”) and 3 partial responses (“PR”). In addition, 8 patients achieved stable disease (“SD”), resulting in a disease control rate of 71%. Median progression-free survival was 5.9 months with median follow-up of 7.4 months. Importantly 3 of 4 responses were ongoing for more than 7 months. All responders were resistant to checkpoint inhibitor treatment prior to the study, which supports the hypothesis that combining AFM24 with atezolizumab may provide an alternative strategy to overcome resistance to existing therapies.

As of May 21, 2024, 21 heavily pretreated *EGFRmut* patients (median of 3 prior therapies) had received the combination therapy of which 13 were response-evaluable. The combination of AFM24 with atezolizumab showed encouraging signals of clinical activity including 1 CR, 3 PRs and 6 patients with SD. As of the data cut-off, all responses were on-going. *EGFRmut* NSCLC is considered an immunogenically weak subtype where single-agent therapy with immune checkpoint inhibitors have exhibited poor response rates. The data suggests that the combination of AFM24 and atezolizumab could be acting synergistically to improve efficacy outcomes.

AFM24 and atezolizumab combination therapy demonstrated a manageable safety profile. Side effects were consistent with the known safety profiles of these agents. The most frequent side effects observed were mild to moderate infusion related reactions and transient mild to moderate increase in liver enzymes.

The *EGFRwt* NSCLC cohort of the study will enroll up to 40 patients and the *EGFRmut* NSCLC cohort will enroll up to 25 patients. Recruitment in both cohorts is ongoing, and further updates are expected in H2 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<sup>®</sup> platform, its ongoing and planned preclinical development and clinical trials, its corporate restructuring, the associated headcount reduction and the impact this may have on Company’s anticipated savings and total costs and expenses, 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 AlloNK<sup>®</sup> NK cells 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: June 3, 2024

**AFFIMED N.V.**

By: /s/ Andreas Harstrick

Name: Andreas Harstrick

Title: Interim Chief Executive Officer, Chief Medical Officer

By: /s/ Denise Mueller

Name: Denise Mueller

Title: Chief Business Officer

---

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Affirmed N.V. Press Release dated June 1, 2024.

**PRESS RELEASE****Affimed Provides Follow-up Data of AFM24 plus Atezolizumab Showing Durable Responses in Heavily Pretreated NSCLC EGFR Wild-type Patients and Positive Initial Data from the NSCLC EGFR Mutant Cohort**

- In 17 EGFR wild-type (*EGFR*wt) non-small cell lung cancer (NSCLC) patients who failed chemotherapy and PD-1/PD-L1, AFM24 plus atezolizumab achieved 4 objective responses; 3 of 4 responses were ongoing for more than 7 months and progression free survival (PFS) was 5.9 months
- Objective responses were also seen in 4 of 13 response-evaluable *EGFR* mutant (*EGFR*mut) NSCLC patients confirming the activity of AFM24 and atezolizumab in heavily pretreated NSCLC patients
- In both NSCLC cohorts, the combination therapy shows a manageable safety profile
- Company to host a conference call / webcast today at 6:00 p.m. CDT / 7:00 p.m. EDT to discuss the updated data from the AFM24-102 trial

**Mannheim, Germany, June 1, 2024** – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, today announced longer follow-up data from the *EGFR*wt cohort and initial clinical efficacy data from the *EGFR*mut cohort from the on-going AFM24-102 study in NSCLC.

As of the updated data cutoff on May 13, 2024 for the 17 *EGFR*wt patients previously reported on, 15 patients were response-evaluable. Four confirmed objective responses were seen: 1 complete response (CR) and 3 partial responses (PR). In addition, 8 patients achieved stable disease (SD), resulting in a disease control rate of 71%. Median progression-free survival was 5.9 months with median follow-up of 7.4 months. Importantly 3 of 4 responses were ongoing for more than 7 months. All responders were resistant to checkpoint inhibitor treatment prior to the study, which supports the hypothesis that combining AFM24 with atezolizumab may provide an alternative strategy to overcome resistance to existing therapies.

As of May 21, 2024, 21 heavily pretreated *EGFR*mut patients (median of 3 prior therapies) had received the combination therapy of which 13 were response-evaluable. The combination of AFM24 with atezolizumab showed encouraging signals of clinical activity including 1 CR, 3 PRs and 6 patients with SD. As of the data cut-off, all responses were on-going. *EGFR*mut NSCLC is considered an immunogenically weak subtype where single-agent therapy with immune checkpoint inhibitors have exhibited poor response rates. The data suggests that the combination of AFM24 and atezolizumab could be acting synergistically to improve efficacy outcomes.

AFM24 and atezolizumab combination therapy demonstrated a manageable safety profile. Side effects were consistent with the known safety profiles of these agents. The most frequent side effects observed were mild to moderate infusion related reactions and transient mild to moderate increase in liver enzymes.

“The efficacy of the combination of AFM24 and atezolizumab in these heavily pretreated NSCLC patients is encouraging and supports our hypothesis of a synergistic activity of AFM24 with PD-1/PD-L1 blockade. We believe the durability of the responses in *EGFR*wt tumors is remarkable and is unlikely driven by checkpoint blockade alone, as all patients with responses had documented progression on their previous PD-1/PD-L1 therapy. In addition, median PFS of atezolizumab, even in checkpoint naïve patients, is only 2.8 months,” said Dr. Andreas Harstrick, Chief Medical and acting Chief Executive Officer of Affimed. “This growing body of evidence reinforces our belief that AFM24 in combination with check point targeting can address pressing unmet medical needs in refractory NSCLC patients.”

The *EGFR*wt NSCLC cohort of the study will enroll up to 40 patients and the *EGFR*mut NSCLC cohort will enroll up to 25 patients. Recruitment in both cohorts is ongoing, and further updates are expected in H2 2024.

### **Conference Call and Webcast Information**

Affimed will host a conference call and webcast for the financial community on June 1, 2024, at 6:00 p.m. CDT / 7:00 p.m. EDT. Dr. Harstrick and Dr. Hye Ryun Kim, Professor at Yonsei University College of Medicine, Seoul, Korea, will review the latest clinical findings and address questions.

The conference call will be available via phone and webcast. The live audio webcast of the call will be available in the “Webcasts” section on the “Investors” page of the Affimed website at <https://www.affimed.com/investors/webcasts-and-corporate-presentation/>. To access the call by phone, please use link: <https://register.vevent.com/register/B1ff607338e5d247f99b548240be2ad413>, and you will be provided with dial-in details and a pin number.

### **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 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 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 corporate restructuring, the associated headcount reduction and the impact this may have on Company's anticipated savings and total costs and expenses, 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 AlloNK<sup>®</sup> NK cells 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: [a.fudukidis@affimed.com](mailto:a.fudukidis@affimed.com)  
Tel.: +1 (917) 436-8102

### **Media Contact**

Mary Beth Sandin  
Vice President, Marketing and Communications  
E-Mail: [m.sandin@affimed.com](mailto:m.sandin@affimed.com)