# 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 May, 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 May 23, 2024, Affimed N.V. (the "Company" or "Affimed") issued a press release titled "Affimed Announces Update of AFM24-102 Study in EGFR Wild-Type Non-Small Cell Lung Cancer at the Annual Meeting of the American Society of Clinical Oncology 2024" announcing an ongoing AFM24-102 phase 2 study update that includes data from patients with epidermal growth factor receptor ("EGFR")-wildtype ("wt") non-small cell lung cancer ("NSCLC").

As of the March 18 cut-off for the poster, 17 patients with *EGFR*wt NSCLC received the combination treatment and 15 patients were response evaluable. One patient showed a confirmed complete response, and three patients showed confirmed partial responses. In addition, seven patients achieved stable disease, resulting in a disease control rate of 73.3% (11/15 patients). Median progression-free survival was 5.9 months.

All responders were resistant to checkpoint inhibitor treatment prior to the study, which supports the hypothesis that combining AFM24 with atezolizumab may enhance the cancer-immunity cycle and provide an alternative strategy to overcome resistance to existing therapies for EGFR-expressing tumors.

AFM24 and atezolizumab were given at their respective single agent doses. Treatment in these heavily pretreated patients was well tolerated. 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.

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, 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® 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: May 23, 2024

### AFFIMED N.V.

By: /s/ Denise Mueller

Name: Denise Mueller Title: Chief Business Officer

By: /s/ Andreas Harstrick

Name: Andreas Harstrick Title: Interim Chief Executive Officer, Chief Medical Officer

## EXHIBIT INDEX

## Exhibit Description of Exhibit

99.1 Affimed N.V. Press Release dated May 23, 2024.



#### PRESS RELEASE

#### Affimed Announces Positive Early Efficacy and Progression Free Survival Results of AFM24-102 Study in EGFR Wild-Type Non-Small Cell Lung Cancer at the Annual Meeting of the American Society of Clinical Oncology 2024

- In 15 response-evaluable patients with metastatic EGFR wild-type NSCLC, who were pretreated with platinum doublet chemotherapy and checkpoint inhibitors, the combination of AFM24 and atezolizumab led to a disease control rate of 73.3% (11/15), including 4 objective responses (1 complete and 3 partial responses)
- As of the March 18, 2024 data cut-off, the median progression free survival was 5.9 months and 3 of 4 responses were ongoing
- The poster of the ongoing study will be presented on June 1, 2024, 9:00 a.m. 12:00 p.m. CDT
- Company to host a conference call / webcast on June 1, 2024 at 6:00 p.m. CDT / 7:00 p.m. EDT to discuss updated results and to present initial clinical efficacy data from the non-small cell lung cancer EGFR mutant cohort of the study

**Mannheim, Germany, May 23, 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 that an update from the Company's AFM24-102 study in advanced EGFR wild-type (*EGFR*wt) non-small cell lung cancer (NSCLC) will be presented at the annual meeting of the American Society of Clinical Oncology (ASCO) to be held in Chicago on May 31 – June 4, 2024. Patients in the study are treated with the combination of AFM24, Affimed's innate cell engager (ICE<sup>®</sup>), and atezolizumab, Roche's checkpoint inhibitor (CPI).

As of the March 18 cut-off for the poster, 17 patients with *EGFR*wt NSCLC received the combination treatment and 15 patients were response evaluable. One patient showed a confirmed complete response, and three patients showed confirmed partial responses (PR). In addition, seven patients achieved stable disease, resulting in a disease control rate of 73.3% (11/15 patients). Median progression-free survival was 5.9 months.

All responders were resistant to checkpoint inhibitor treatment prior to the study, which supports the hypothesis that combining AFM24 with atezolizumab may enhance the cancer-immunity cycle and provide an alternative strategy to overcome resistance to existing therapies for EGFR-expressing tumors.

AFM24 and atezolizumab were given at their respective single agent doses. Treatment in these heavily pretreated patients was well tolerated. 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.

"We are very encouraged to see objective and lasting responses in patients who have failed multiple lines of therapy including platinum doublets and checkpoint inhibitors," said Dr. Andreas Harstrick, Chief Medical and acting Chief Executive Officer of Affimed. "These data support our hypothesis that the combination of AFM24 and PD-1 targeting may act synergistically on the immunity cycle. It is remarkable that this can be achieved with a chemotherapy-free approach. We are committed to continuing clinical development of this therapy and are enrolling additional patients for both *EGFRwt* and *EGFRmut* NSCLC."

The EGFRwt NSCLC cohort of the study will enroll up to 40 patients and the EGFRmut NSCLC cohort will enroll up to 25 patients.

The full data set will be presented by Dr. Hye Ryun Kim, Professor at Yonsei University College of Medicine, Seoul, Korea, at ASCO on June 1, 2024, during the poster session on Developmental Therapeutics—Immunotherapy (9:00 a.m.—12:00 p.m. CDT).

The abstract and more details about the ASCO conference are available online at <u>Attend | ASCO Annual Meeting</u>. The poster will be available online at <u>https://www.affimed.com/</u>after the presentation.

#### **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.

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 <u>https://www.affimed.com/investors/webcasts-and-corporate-presentation/</u>. To access the call by phone, please use link:

https://register.vevent.com/register/BIff607338e5d247f99b548240be2ad413, 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.

#### **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," "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, 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® 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: <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>