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, 2023

Commission File Number: 001-36619

Affimed N.V.

Im Neuenheimer Feld 582,
69120 Heidelberg,
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 3, 2023, Affimed N.V. (Nasdaq: AFMD) ("Affimed," or the "Company") issued a press release titled "Affimed Presents AFM24 Monotherapy Data in Non-Small Cell Lung Cancer at the Annual Meeting of the American Society of Clinical Oncology and Provides Strategic Update on AFM24 Development Plan" announcing the presentation at the American Society of Clinical Oncology Annual Meeting of safety and efficacy data from the EGFR mutant NSCLC expansion cohort of its ongoing Phase 1/2 study investigating innate cell engager AFM24 as monotherapy. The data included 15 evaluable patients and showed encouraging early signs of clinical activity including confirmed partial responses and durable stable disease. EGFR mutant NSCLC is a very aggressive and resistant tumor type in which most classical NSCLC treatments achieve limited to no clinical activity, especially in more advanced patients. Affimed's innate cell engager AFM24 aims to reactivate the innate and consequently the adaptive immune system to recognize and destroy EGFR mutant tumors.

At the planned interim analysis, 15 patients with EGFR mutant NSCLC and a median of 2 prior lines of therapy had been treated with a median of 11 doses of AFM24. As of the cut-off date, the data showed clinical activity and signals of anti-tumor activity in 7 out of 15 heavily pre-treated patients, including two confirmed partial responses and five patients with stable disease (SD) resulting in an objective response rate of 13% and a disease control rate of 47%. All patients with stable disease were progression free for at least 3.5 months, with one patient exhibiting ongoing SD for more than 8 months. A reduction in tumor burden was observed in five of 13 patients (38%) with available baseline and subsequent tumor assessments based on RECIST criteria. All patients showed a well-managed safety profile with the majority exhibiting mild-to-moderate treatment-related adverse events in-line with previous findings, highlighting the well-managed safety profile that makes AFM24 a candidate for combination approaches. One Grade 5 (pneumonitis) adverse event was reported in a patient with progressive disease and multiple comorbidities; however, since relation to AFM24 could not be ruled out it is deemed treatment related. Although the formal continuation criteria for the cohort were not met, these data provide proof of concept that targeting NK cells can induce remission in patients with especially hard-to-treat solid tumors.

INCORPORATION BY REFERENCE

Exhibit 99.1 to this Report on Form 6-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

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.

AFFIMED N.V.

Date: June 4, 2023

By: /s/ Adi Hoess
Name: Adi Hoess
Title: Chief Executive Officer

By: /s/ Angus Smith
Name: Angus Smith
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Affimed N.V. Press Release dated June 3, 2023.

PRESS RELEASE

Affimed Presents AFM24 Monotherapy Data in Non-Small Cell Lung Cancer at the Annual Meeting of the American Society of Clinical Oncology and Provides Strategic Update on AFM24 Development Plan

- Data update from AFM24-101 phase 1/2 monotherapy study includes 15 patients from the EGFR mutant non-small cell lung cancer (NSCLC) cohort
- AFM24 showed clinical activity in 7 out of 15 heavily pre-treated patients with tumor reductions, including 2 confirmed partial responses and 5 patients exhibiting stable disease
- In line with previous results, the majority of patients experienced only mild to moderate treatment-related adverse events, confirming a well-manageable safety profile in heavily pretreated patients, an important factor for combination regimens
- Based on the totality of data available to date, Affimed will focus clinical development of AFM24 on combination approaches, adding an EGFR mutant NSCLC cohort to the AFM24-102 study to evaluate therapeutic potential in combination with Roche's PD-L1 checkpoint inhibitor atezolizumab
- Company to host a conference call / webcast today at 6:00 p.m. CDT / 7:00 p.m. EDT to discuss the latest data and AFM24 development strategy for moving forward with the combination approach

Heidelberg, Germany, June 3, 2023 – 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 the presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting of safety and efficacy data from the EGFR mutant NSCLC expansion cohort of its ongoing Phase 1/2 study investigating innate cell engager (ICE®) AFM24 as monotherapy. The data included 15 evaluable patients and showed encouraging early signs of clinical activity including confirmed partial responses and durable stable disease. EGFR mutant NSCLC is a very aggressive and resistant tumor type in which most classical NSCLC treatments achieve limited to no clinical activity, especially in more advanced patients. Affimed's innate cell engager AFM24 aims to reactivate the innate and consequently the adaptive immune system to recognize and destroy EGFR mutant tumors.

“The treatment options for patients with advanced solid tumors and EGFR alterations are limited by the development of resistance to existing EGFR targeting therapies and by modest activity of checkpoint inhibitors. The results we have seen with AFM24 monotherapy in an expansion cohort of advanced, refractory NSCLC patients with EGFR mutations indicate that activating the innate immune pathway in this patient population results in anti-tumor activity and may offer a novel therapeutic approach. Given the underlying molecular pathways, we believe that AFM24 could potentially enable checkpoint inhibitors to achieve a positive effect,” said Dr. Anthony El-Khoueiry, Associate Director of Clinical Research at USC Norris Comprehensive Cancer Center and principal investigator of the AFM24 studies.

The AFM24 EGFR mutant NSCLC cohort is part of the AFM24-101 open-label, non-randomized, multi-center, phase 1/2a study (NCT04259450) investigating the safety, tolerability, and preliminary efficacy of AFM24 monotherapy in patients with advanced or metastatic EGFR+ solid tumors. Other cohorts being investigated included colorectal cancer (CRC) and renal carcinoma (RCC).

At the planned interim analysis, 15 patients with EGFR mutant NSCLC and a median of 2 prior lines of therapy had been treated with a median of 11 doses of AFM24. As of the cut-off date, the data showed clinical activity and signals of anti-tumor activity in 7 out of 15 heavily pre-treated patients, including two confirmed partial responses and five patients with stable disease (SD) resulting in an objective response rate of 13% and a disease control rate of 47%. All patients with stable disease were progression free for at least 3.5 months, with one patient exhibiting ongoing SD for more than 8 months. A reduction in tumor burden was observed in five of 13 patients (38%) with available baseline and subsequent tumor assessments based on RECIST criteria. All patients showed a well-managed safety profile with the majority exhibiting mild-to-moderate treatment-related adverse events in-line with previous findings, highlighting the well-managed safety profile that makes AFM24 a candidate for combination approaches. One Grade 5 (pneumonitis) adverse event was reported in a patient with progressive disease and multiple comorbidities; however, since relation to AFM24 could not be ruled out it is deemed treatment related. Although the formal continuation criteria for the cohort were not met, these data provide proof of concept that targeting NK cells can induce remission in patients with especially hard-to-treat solid tumors.

“We believe that AFM24 can be an important addition to the treatment armamentarium for addressing EGFR mutant tumors as the early anti-tumor effects support further evaluation in a combination setting with the goal of achieving meaningful patient benefit. That is why we are adding an EGFR mutant NSCLC cohort to our ongoing phase 1/2 study in combination with Roche’s PD-L1 checkpoint inhibitor atezolizumab,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. “Our broad AFM24 program aimed at identifying the right therapeutic settings and indications, and we believe that the data generated to date allow us to build the right path forward to maximize patient benefit.”

Strategic Development of AFM24

Based on the totality of the data accumulated for AFM24 to date, Affimed will focus its near-term development efforts on advancing AFM24 in combination with checkpoint inhibitors as part of its ongoing AFM24-102 study to further investigate the synergies between AFM24 and atezolizumab. Enrollment in the AFM24-101 monotherapy study will be concluded. An expansion cohort investigating EGFR mutant NSCLC will be added to AFM24-102 based on the encouraging signals observed in AFM24-101. Enrollment for the AFM24-102 combination study is ongoing with early encouraging case studies from the dose escalation supporting the hypothesis of combining innate and adaptive immunotherapy approaches in EGFR-positive solid tumors. An initial data update from the dose escalation and expansion part of the study is expected in the second half of 2023.

AFM24 is also currently being investigated in combination with an autologous NK cell product together with NKGen Biotech. The dose escalation part of this study is ongoing and initial data are expected to be available in H2 2023. Affimed and NKGen have mutually decided to discontinue the study. In line with Affimed's NK cell combination experience for AFM13, the Company will evaluate the best options to advance this project with an allogeneic off-the-shelf NK cell product which the Company expects to be better suited for combination with AFM24 in a highly advanced patient population.

The Company will provide further details, including data from all three AFM24 monotherapy cohorts, and guidance on the clinical development plan for AFM24 in a conference call and webcast scheduled today.

Conference Call and Webcast Information

Affimed will host a conference call and webcast on June 3, 2023, at 6:00 p.m. CDT / 7:00 p.m. EDT to review the monotherapy data and provide a strategic update on the AFM24 program going forward.

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/BIca5147f060da49d5963a0b00a7bc8a66 , and you will be provided with dial-in details and a pin number.

Note: To avoid delays, we encourage participants to dial into the conference call 15 minutes ahead of the scheduled start time. A replay of the webcast will be accessible at the same link for 30 days following the call.

More details about the programs for the ASCO Annual Meetings are available online at www.asco.org

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.

Affimed is evaluating AFM24 as monotherapy and in combinations with other cancer treatments in patients with advanced EGFR-expressing solid malignancies whose disease has progressed after treatment with previous anticancer therapies.

AFM24-101, a monotherapy, first-in-human phase 1/2a open-label, is a non-randomized, multi-center, multiple ascending dose escalation and expansion study. Additional details may be found at www.clinicaltrials.gov using the identifier NCT04259450.

AFM24 is also being evaluated in a phase 1/2a study in combination with Roche's PD-L1 checkpoint inhibitor atezolizumab (AFM24-102, NCT05109442).

Furthermore, Affimed and NKGen Biotech are investigating AFM24 in combination with NKGen Biotech's NK cell SNK01 in a phase 1/2a study (AFM24-103, NCT05099549).

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 Heidelberg, Germany, with offices in New York, NY, 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: www.affimed.com.

Forward-Looking Statements

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.

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