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 December, 2023

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 December 11, 2023, Affimed N.V. (Nasdaq: AFMD) ("Affimed" or the "Company") issued a press release titled "Affimed Announces Positive Data for AFM24 in Combination with the PD-L1 Checkpoint Inhibitor Atezolizumab in Heavily Pre-treated EGFR-Wildtype Non-Small Cell Lung Cancer Patients" announcing interim safety and efficacy data on its innate cell engager (ICE®) AFM24 from the ongoing AFM24-102 combination study with atezolizumab, an anti-PD-L1 checkpoint inhibitor, in patients with advanced Epidermal Growth Factor Receptor (EGFR)-expressing solid tumors. The data update as of December 6th, 2023, includes 15 patients from the EGFR-wildtype non-small cell lung cancer (NSCLC) cohort with a median of 2 prior lines of therapy. Importantly, all patients were pretreated with and ultimately progressed while on PD-[L]1 targeting therapy.

The combination of AFM24 with atezolizumab showed encouraging signals of clinical activity, including 1 unconfirmed complete response (CR), 3 partial responses (PR) (1 confirmed, 2 unconfirmed) and 7 patients exhibiting stable disease (SD). All eleven patients with a CR, unconfirmed response or SD (73%) are continuing treatment, with 4 patients exceeding 3 months of therapy; 2 patients improved from SD at the first scan to PR at the second scan based on Response Evaluation Criteria in Solid Tumours (RECIST) criteria.

AFM24 has demonstrated a positive safety and tolerability profile as both a monotherapy and in combination therapy. The combination with atezolizumab has not led to unexpected toxicity, and the toxicity observed to date is in line with the toxicity profile of the individual agents alone. The majority of patients experienced only mild to moderate treatment-related adverse events.

Affimed also announced that it has discontinued enrollment in AFM24-102 into the gastric cancer cohort and the basket cohort evaluating pancreatic cancer, biliary tract cancer and hepatocellular carcinoma. While clinical activity was observed in both cohorts, neither cohort is likely to achieve response rates that would meet the Company's efficacy hurdle and the Company's strategic focus is to advance the NSCLC program as fast as possible.

On December 11, 2023, the Company issued a press release titled "Affimed Announces Updated Phase 1/2 Data from Acimtamig in Combination with Allogeneic NK in Hodgkin Lymphoma Patients Who Failed Prior Chemotherapy and Are Double-Refractory to Brentuximab Vedotin (BV) and Checkpoint Inhibitors (CPIs)" announcing updated data on its lead ICE® acimtamig.

A total of 42 patients were enrolled in the study with 36 patients treated at the recommended phase 2 dose level (RP2D). 32 of the 36 patients treated at the RP2D were relapsed/refractory Hodgkin Lymphoma (HL) patients. All 32 HL patients were heavily pretreated with multiple lines of chemotherapy, all had previously received CPIs and BV, and were refractory to their most recent line of therapy with active progressive disease at the time of enrollment. Across all dose levels, the treatment regimen achieved an objective response rate (ORR) of 93% with a CR rate of 67%; among the 32 HL patients treated at the RP2D the treatment regimen achieved an ORR of 97% and a CR rate of 78%. In addition, the treatment regimen demonstrated a good safety and tolerability profile with no cases of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome or graft versus host disease of any grade. Mild to moderate infusion related reactions were seen in 7.7% of the acimtamig infusions.

Across all dose levels, median event free survival (EFS) was 8.8 months and median overall survival was not reached. For the HL patients treated at the RP2D, median EFS was 9.8 months - with 84% patients alive at 12 months. The median duration of response was 8.8 months and 72% CR assessed at 6 months for HL patients treated at the RP2D; 30% of patients with complete response remained in CR beyond 12 months.

Copies of the press releases are attached hereto as Exhibits 99.1 and 99.2 and are 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.

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 in Mannheim, Germany, on December 11, 2023.

AFFIMED N.V.

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 December 11, 2023.
99.2	Affimed N.V. Press Release dated December 11, 2023.

PRESS RELEASE

Affimed Announces Positive Data for AFM24 in Combination with the PD-L1 Checkpoint Inhibitor Atezolizumab in Heavily Pre-treated EGFR-Wildtype Non-Small Cell Lung Cancer Patients

- Data update from AFM24-102 Phase 1/2a combination study includes 15 heavily pre-treated patients from the EGFR-wildtype non-small cell lung cancer (NSCLC) expansion cohort
- Responses observed in 4 of 15 patients, including 1 confirmed partial response (PR), 1 unconfirmed complete response (CR) awaiting confirmation, 2 unconfirmed PRs awaiting confirmation; an additional 7 of 15 patients exhibiting stable disease (SD) leading to a disease control rate of 73%
- Tumor shrinkage observed in 7 of 15 (47%) patients
- All patients were pretreated with and ultimately progressed while on PD-[L]1 targeting therapy
- The majority of patients experienced only mild to moderate treatment-related adverse events, confirming a well-manageable safety profile in combination with atezolizumab
- Company to host a conference call / webcast today at 4:30 p.m. EST to discuss the data

Mannheim, Germany, December 11, 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, announced interim safety and efficacy data on its innate cell engager (ICE®) AFM24 from the ongoing AFM24-102 combination study with atezolizumab, an anti-PD-L1 checkpoint inhibitor, in patients with advanced EGFR-expressing solid tumors. The data update as of December 6th, 2023, includes 15 patients from the EGFR-wildtype NSCLC cohort with a median of 2 prior lines of therapy. Importantly, all patients were pretreated with and ultimately progressed while on PD-[L]1 targeting therapy.

The combination of AFM24 with atezolizumab showed encouraging signals of clinical activity, including 1 unconfirmed CR, 3 PRs (1 confirmed, 2 unconfirmed) and 7 patients exhibiting SD. All eleven patients with a confirmed response, unconfirmed response or stable disease (73%) are continuing treatment, with 4 patients exceeding 3 months of therapy; 2 patients improved from SD at the first scan to PR at the second scan based on RECIST criteria.

"Most patients with advanced NSCLC will need additional treatment after first-line therapy, and currently available options for patients in the 2L+ setting provide only modest response rates and short progression-free survival," said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. "Given the severity of this cancer and the urgent need for new treatments, we are very encouraged by the early safety and efficacy results demonstrated by the combination of AFM24 and atezolizumab in this cohort. We look forward to seeing the data in this cohort mature as well as to sharing data from the EGFR-mutant NSCLC cohort, anticipated in the first half of 2024."

Affimed's ICE® AFM24, in combination with atezolizumab, has the potential to reactivate the innate and consequently the adaptive immune system to recognize and destroy EGFR-positive NSCLC tumors. Considering the low ORR reported on atezolizumab monotherapy in checkpoint inhibitor—relapsing and refractory patients, Affimed believes the clinical activity observed in AFM24-102 is likely due to the synergy of AFM24 with atezolizumab.

AFM24 has demonstrated a positive safety and tolerability profile as both a monotherapy and in combination therapy. The combination with atezolizumab has not led to unexpected toxicity, and the toxicity observed to date is in line with the toxicity profile of the individual agents alone. The majority of patients experienced only mild to moderate treatment-related adverse events.

Affimed also announced that it has discontinued enrollment in AFM24-102 into the gastric cancer cohort and the basket cohort evaluating pancreatic cancer, biliary tract cancer and hepatocellular carcinoma. While clinical activity was observed in both cohorts, neither cohort is likely to achieve response rates that would meet the Company's efficacy hurdle and the Company's strategic focus is to advance the NSCLC program as fast as possible.

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/BIb2258d6c5f5a474cad74869a7b7b1bb5, 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.

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 EGRF-expressing advanced solid malignancies whose disease has progressed after treatment with previous anticancer therapies (NCT05109442).

The Company also announced data from the phase 1/2 data study of acimtamig in combination with allogeneic NK in relapsed/refractory Hodgkin Lymphoma patients conducted at the University of Texas MD Anderson Cancer Center. The Company will host a call today at 1:30 p.m. PST / 4:30 p.m. EST / 22:30 CET to discuss both the acimtamig and AFM24 clinical data updates and to provide an update on the status of the acimtamig LuminICE-203 study, AFM13-104.

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.

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, 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 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.

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PRESS RELEASE

Affimed Announces Updated Phase 1/2 Data from Acimtamig in Combination with Allogeneic NK in Hodgkin Lymphoma Patients Who Failed Prior Chemotherapy and Are Double-Refractory to Brentuximab Vedotin (BV) and Checkpoint Inhibitors (CPIs)

- In 32 patients with relapsed/refractory (r/r) Hodgkin lymphoma (HL) treated at the recommended phase 2 dose level (RP2D), the objective response rate (ORR) was 97% and the complete response (CR) rate was 78%
- In this cohort median EFS was 9.8 months with 84% patients alive at 12 months, and median duration of response (DoR) was 8.8 months
- Patients were heavily pretreated (median of 7 prior lines), all had previously received CPIs and BV, and were refractory to their most recent line of therapy
- Patients received up to four cycles of therapy and the treatment was well tolerated with no instances of cytokine release syndrome (CRS), graft versus host disease (GvHD) or immune effector cell-associated neurotoxicity syndrome (ICANS)

Mannheim, Germany, December 11, 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, announced updated data on its lead innate cell engager (ICE®) acimtamig. Data from the investigator-initiated trial is being presented today at the American Society of Hematology (ASH) 2023 Annual Meeting by Yago Nieto, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at The University of Texas MD Anderson Cancer Center and principal investigator of the study. Affimed will host a webcast following the presentation to review the data and provide a strategic update on acimtamig's future development.

A total of 42 patients were enrolled in the study with 36 patients treated at the RP2D. 32 of the 36 patients treated at the RP2D were HL patients. All 32 HL patients were heavily pretreated with multiple lines of chemotherapy, all had previously received CPIs and BV, and were refractory to their most recent line of therapy with active progressive disease at the time of enrollment. Across all dose levels, the treatment regimen achieved an ORR of 93% with a CR rate of 67%; among the 32 HL patients treated at the RP2D the treatment regimen achieved an ORR of 97% and a CR rate of 78%. In addition, the treatment regimen demonstrated a good safety and tolerability profile with no cases of CRS, ICANS or GvHD of any grade. Mild to moderate infusion related reactions (IRRs) were seen in 7.7% of the acimtamig infusions.

Across all dose levels, median event free survival (EFS) was 8.8 months and median overall survival (OS) was not reached. For the HL patients treated at the RP2D, median EFS was 9.8 months - with 84% patients alive at 12 months. The median DoR was 8.8 months and 72% CR assessed at 6 months for HL patients treated at the RP2D; 30% of patients with complete response remained in CR beyond 12 months.

“When we conduct studies in a patient population that has failed their previous line of therapy, demonstrating even a modest response is encouraging. To see this magnitude of responses in terms of ORR (97%) and CR (78%) is remarkable and fuels our commitment to bring this therapy to more patients,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. “Building on these results, we are well underway with our Phase 2 LuminICE-203 study. We have enrolled and dosed patients in the first two cohorts and we look forward to sharing data in the first half of 2024.”

The Company will host a call today at 1:30 p.m. PST / 4:30 p.m. EST / 22:30 CET to discuss the data presented at ASH and provide a strategic update. 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 the link: https://register.vevent.com/register/BIb2258d6c5f5a474cad74869a7b7b1bb5, 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.

About the AFM13-104 Phase 1/2 Study

The University of Texas MD Anderson Cancer Center is studying acimtamig (AFM13) in an investigator-sponsored phase 1/2 trial in combination with cord blood-derived allogeneic NK cells in patients with recurrent or refractory CD30-positive lymphomas. The study is a dose-escalation trial of precomplexed NK cells, followed by an expansion phase that recruited 36 patients with r/r CD30 positive lymphomas, treated with the RP2D of 1×10^8 NK cells/kg followed by three weekly doses of 200 mg acimtamig monotherapy. Each treatment cycle consists of lymphodepleting chemotherapy with fludarabine (30 mg/m² per day) and cyclophosphamide (300 mg/m² per day) followed two days later by a single infusion of cytokine-preactivated and expanded cord blood-derived NK cells that are pre-complexed with acimtamig. Three weekly infusions of acimtamig (200 mg) monotherapy are subsequently administered and responses are assessed by the investigator on day 28 by FDG-PET.

MD Anderson has an institutional financial conflict of interest with Affimed related to this research and has therefore implemented an Institutional Conflict of Interest Management and Monitoring Plan. Additional information about the study can be found at www.clinicaltrials.gov (NCT04074746).

About Acimtamig

Acimtamig (AFM13) is a first-in-class innate cell engager (ICE®) that uniquely activates the innate immune system to destroy CD30-positive hematologic tumors. Acimtamig induces specific and selective killing of CD30-positive tumor cells, leveraging the power of the innate immune system by engaging and activating natural killer (NK) cells and macrophages. Acimtamig is a tetravalent bispecific innate cell engager designed to act as a bridge between the innate immune cells and the tumor creating the necessary proximity for the innate immune cells to specifically destroy the tumor cells.

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, 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.

About AlloNK® and Artiva

Artiva is an immunotherapy company with the ability to produce off-the-shelf, allogeneic NK cell therapies at a massive scale. Artiva's mission is to develop effective, safe and accessible cell therapies for patients with devastating autoimmune diseases and cancers. Artiva's lead program, AlloNK® (also known as AB-101), is an allogenic, non-genetically modified NK cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity (ADCC) effect of monoclonal antibodies or NK cell engagers. AlloNK is a cryopreserved, off-the-shelf therapy with the potential to be administered in the community setting. Using the company's cell therapy manufacturing platform, Artiva can generate thousands of doses of cryopreserved, infusion-ready AlloNK cells from a single umbilical cord blood unit while retaining high and consistent expression of CD16 and other activating NK receptors. Artiva is headquartered in San Diego. For more information, visit **www.artivabio.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 acimtamig, 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 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® 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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