# 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, 2022**

**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 December 10, 2022, Affimed N.V. (Nasdaq: AFMD) ("Affimed," or the "Company") issued a press release titled "Affimed Provides Updated Clinical Data from Phase 1/2 Study of AFM13 Precomplexed with Cord Blood-Derived NK Cells at the ASH 2022 Annual Meeting" providing a data update from the ongoing phase 1/2 study of the Company's lead innate cell engager (ICE®) AFM13 precomplexed with cord blood-derived natural killer (cbNK) cells in patients with CD30-positive relapsed or refractory (R/R) Hodgkin and Non-Hodgkin lymphomas. The results are being presented today at the 64th American Society of Hematology (ASH) Annual Meeting by principal investigator Yago Nieto, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at The University of Texas MD Anderson Cancer Center. Results from the study continue to demonstrate high objective and complete response rates with a well-tolerated safety profile.

Duration of response (DOR) continues to be monitored, and key observations as of the cutoff date include:

- 63% of patients with at least 6 months follow-up after initial infusion (n=24) remain in complete response (CR) rate for at least 6 months;
- 18 of 33 responders at the recommended phase 2 dose (RP2D) remain in response as of the cutoff date, including 17 of 25 patients with a CR rate; and
- Five patients treated at the RP2D had their response consolidated with a stem cell transplant

The treatment continues to be well tolerated in the larger patient population, with minimal side effects beyond the expected myelosuppression from the preceding lymphodepleting chemotherapy. No instances of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft versus host disease were observed. There were 20 infusion-related reactions in 294 infusions (6.8%) of AFM13 alone and one infusion-related reaction in 99 infusions (1%) of the cbNK cells precomplexed with AFM13. No dose-limiting toxicities were encountered.

On December 10, 2022, the Company issued a press release titled "Affimed Reports Topline Data from AFM13 Monotherapy Phase 2 REDIRECT Study in Patients with Relapsed or Refractory Peripheral T Cell Lymphoma" announcing topline data from its phase 2 REDIRECT study investigating AFM13 monotherapy in patients with advanced-stage R/R Peripheral T Cell Lymphoma.

Primary efficacy measures include objective response rate of 32.4% and a CR rate of 10.2%. Key secondary and exploratory outcome measures include safety, durability of response, progression free survival (PFS) and overall survival (OS). The safety profile of AFM13 was well managed and consistent with previously reported data of prior and ongoing clinical studies with AFM13. Median DoR was 2.3 months, median PFS was 3.5 months and median OS was 13.8 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.

**AFFIMED N.V.**

Date: December 12, 2022

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 10, 2022. |
| 99.2 | Affimed N.V. Press Release dated December 10, 2022. |

**Exhibit 99.1**

**PRESS RELEASE**

**Affimed Provides Updated Clinical Data from Phase 1/2 Study of AFM13 Precomplexed with Cord Blood-Derived NK Cells at the ASH 2022 Annual Meeting**

- AFM13 in combination with NK cells shows very high overall and complete response rates in 41 heavily pre-treated CD30-positive Hodgkin lymphoma (HL) and Non-Hodgkin lymphoma (NHL) patients
- Patients had a median of seven prior lines of treatment; of note, all patients failed to demonstrate objective response to immediate prior line of therapy
- 31 Hodgkin lymphoma patients treated at the recommended phase 2 dose (RP2D) showed an objective response rate (ORR) of 97% and a complete response (CR) rate of 77%
- Three of four NHL patients treated at the RP2D achieved an objective response, including one CR
- 63% of patients treated at the RP2D with at least 6 months follow-up after initial infusion (n=24) remain in complete response for at least 6 months
- Treatment continues to be well tolerated; no instances of cytokine release syndrome, immune effector cell-associated neurotoxicity or graft versus host disease observed
- Affimed to host investor event and webcast today at 4:00 p.m. CST / 5:00 p.m. EST to discuss the development plan for AFM13

**Heidelberg, Germany, December 10, 2022 –** 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 a data update from the ongoing phase 1/2 study of the Company's lead innate cell engager (ICE®) AFM13 precomplexed with cord blood-derived natural killer (cbNK) cells in patients with CD30-positive relapsed or refractory Hodgkin and Non-Hodgkin lymphomas. The results are being presented today at the 64th American Society of Hematology (ASH) Annual Meeting by principal investigator Yago Nieto, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at The University of Texas MD Anderson Cancer Center. Results from the study continue to demonstrate high objective and complete response rates with a well-tolerated safety profile.

In 31 patients with Hodgkin lymphoma treated at the RP2D, an ORR of 97% and a CR rate of 77% were observed. In four non-Hodgkin lymphoma patients treated at the RP2D, three objective responses, including one CR in a patient with peripheral T-cell lymphoma, were observed. Across all 35 patients treated at the RP2D, a 94% ORR and a CR rate of 71% were observed.

“It’s impressive that we continue to see these response rates in a patient population that has exhausted all other treatment options. As a physician, when I consider that all patients in this study did not respond to their previous line of treatment, these results are especially meaningful,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed.

Duration of response (DOR) continues to be monitored, and key observations as of the cutoff date include:

- 63% of patients with at least 6 months follow-up after initial infusion (n=24) remain in CR for at least 6 months
- 18 of 33 responders at the RP2D remain in response as of the cutoff date, including 17 of 25 patients with a CR
- Five patients treated at the RP2D had their response consolidated with a stem cell transplant

The treatment continues to be well tolerated in the larger patient population, with minimal side effects beyond the expected myelosuppression from the preceding lymphodepleting chemotherapy. No instances of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft versus host disease were observed. There were 20 infusion-related reactions in 294 infusions (6.8%) of AFM13 alone and one infusion-related reaction in 99 infusions (1%) of the cord blood-derived NK cells precomplexed with AFM13. No dose-limiting toxicities were encountered.

“These data further confirm that combining our AFM13 innate cell engager with cord blood-derived natural killer cells has the potential to provide a truly transformative treatment for patients with limited therapeutic options,” commented Dr. Adi Hoess, Chief Executive Officer at Affimed. “Our focus and commitment together with our new partner Artiva is expected to bring AFM13 in combination with NK cells to the market as quickly as possible for the benefit of patients with CD30-positive lymphomas.”

AFM13, a bispecific tetravalent ICE® molecule, is designed for high affinity binding, both to CD16A on NK cells and macrophages, and to CD30 on lymphoma cells.

**Oral Presentation Details**

**Title:** Innate Cell Engager AFM13 Combined with Preactivated and Expanded Cord Blood-Derived NK Cells for Patients with Double Refractory CD30+ Lymphoma
**Session:** Cellular Immunotherapies: Early Phase and Investigational Therapies: Lymphoma
**Presentation Date & Time:** Saturday, December 10, 2022, 1:15 p.m. CST
**Location:** Ernest N. Morial Convention Center, La Nouvelle Orleans Ballroom AB

**Investor Event, Conference Call and Webcast Information**

Affimed will host an investor event to review AFM13 clinical data and development plans in CD30-expressing malignancies. The investor event will take place in-person and virtually and a webcast of the event will be available in the "Webcasts" section on the "Investors" page of Affimed's website at https://www.affimed.com/investors/webcasts-and-corporate-presentation/. To access the event via phone, please dial +1 (929) 205-6099 for U.S. callers, or +44 (203) 481-5240 for international callers, and reference meeting ID 847 4106 6227 approximately 15 minutes prior to the call. To reserve your place in the live event, please contact Alex Fudukidis via e-mail at a.fudukidis@affimed.com.

A replay of the webcast/call will be archived on Affimed's website for 30 days after the call.

**About the AFM13-104 Phase 1/2 Study**

The University of Texas MD Anderson Cancer Center is studying 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 recruiting up to 40 patients with r/r CD30 positive lymphomas at the RP2D of $1\times10^8$ NK cells/kg. 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 AFM13. Three weekly infusions of AFM13 (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).

As of the cut-off date, 41 patients with relapsed or refractory CD30-positive Hodgkin and Non-Hodgkin lymphoma were treated in the study, all of whom were evaluable for response. The patients treated in the study have received a median of seven prior lines of therapy. After the first 13 patients treated at the RP2D, the protocol was amended to allow patients to receive up to 4 cycles, whereas previously patients were only eligible for 2 cycles.

**About AFM13**

AFM13 is a first-in-class innate cell engager (ICE®) that uniquely activates the innate immune system to destroy CD30-positive hematologic tumors. AFM13 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. AFM13 is Affimed's most advanced ICE® clinical program and is currently being evaluated as a monotherapy in a registration-directed trial in patients with relapsed/refractory peripheral T-cell lymphoma (REDIRECT). Additional details can be found at www.clinicaltrials.gov (NCT04101331).

**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 trends that may affect the industry or the Company, 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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**Affimed Reports Topline Data from AFM13 Monotherapy Phase 2 REDIRECT Study in Patients with Relapsed or Refractory Peripheral T Cell Lymphoma**

- Data from REDIRECT establish that AFM13 monotherapy is effective in the treatment of relapsed/refractory peripheral T cell lymphoma (r/r PTCL) patients with a differentiated safety profile
- AFM13 demonstrated robust activity on the primary end point with an objective response rate (ORR) of 32.4%
- Other measures of efficacy included median duration of response (DoR) of 2.3 months, median progression free survival (PFS) of 3.5 months and median overall survival (OS) of 13.8 months in advanced-stage r/r PTCL patients who have undergone a mean of 2.7 prior lines of therapy
- Comparable response rates observed in patients with high and low CD30 expression levels and regardless of prior brentuximab vedotin treatment
- Based on substantial synergy observed in AFM13 combined with NK cells in Hodgkin lymphoma, Affimed plans to focus future investment in PTCL on the combination approach of AFM13 with AB-101 NK cells
- Company to discuss results during AFM13 investor event today at 4:00 p.m. CST / 5:00 p.m. EST

**Heidelberg, Germany, December 10, 2022 –** 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 topline data from its phase 2 REDIRECT study investigating AFM13 monotherapy in patients with advanced-stage r/r PTCL.

Primary efficacy measures include ORR of 32.4% and a complete response (CR) rate of 10.2%. Key secondary and exploratory outcome measures include safety, durability of response, progression free survival and overall survival. The safety profile of AFM13 was well managed and consistent with previously reported data of prior and ongoing clinical studies with AFM13. Median DoR was 2.3 months, median PFS was 3.5 months and median OS was 13.8 months.

"These are remarkable data for AFM13 as a single agent and they confirm that the activation of innate immunity can lead to robust clinical activity," said Dr. Adi Hoess, Chief Executive Officer at Affimed. "Our parallel study investigating AFM13 in combination with allogeneic NK cells shows that this combination can materially improve clinical outcomes for patients with CD30-postive lymphomas. We will therefore be focusing further development of AFM13 in PTCL on the combination with NK cells to improve the durability of response and build on the already meaningful activity with the goal of obtaining regulatory approval to give this difficult to treat patient population another therapeutic option."

“The activity of AFM13 in heavily pretreated patients with peripheral T cell lymphoma is very encouraging with an objective response rate of 32% and a PFS of 3.5 months,” said Dr. Won Seog Kim, Professor of Hematology-Oncology at Samsung Medical Center in Seoul and a principal investigator for the study. “The data demonstrate that the innate immune system can successfully attack lymphomas and thus AFM13 provides a new mechanism of action that could expand our options in treating this difficult disease.”

REDIRECT is a registration-directed phase 2 open-label, multicenter, global study investigating the efficacy and safety of AFM13 monotherapy in patients with CD30-positive r/r PTCL. The primary outcome measure was the objective response rate (ORR) following treatment with AFM13 as measured by an independent review committee (IRC) by FDG-PET. Secondary and exploratory outcome measures included DoR, PFS, OS, the safety of AFM13 as well as pharmacokinetics and immunogenicity of AFM13. In the trial, 108 patients received treatment with AFM13 as weekly intravenous infusions of 200 mg for the duration of the trial participation. Disease assessment was conducted at screenings every 8 weeks for the first 2 assessments and every 12 weeks thereafter.

Peripheral T cell lymphomas are highly aggressive and one of the most difficult to treat forms of lymphoma with very poor prognosis for patients. Based on the compelling data seen in Hodgkin lymphoma for the combination of AFM13 with cord blood-derived NK cells in the AFM13-104 study, the Company believes that the combination with AB-101 has a higher probability to deliver increased anti-tumor activity and a more durable clinical benefit to address the unmet need in this patient population. Accordingly, Affimed does not intend to pursue an accelerated approval for AFM13 monotherapy in PTCL and will focus investment on clinical development in the combination of AFM13 with Artiva’s AB-101 NK cell product.

**Investor Event & Webcast Details**

Affimed will host an investor event to review AFM13 clinical data and development plans in CD30 expressing malignancies. The investor event will take place in-person and virtually and a webcast of the event will be available in the “Webcasts” section on the “Investors” page of Affimed’s website at https://www.affimed.com/investors/webcasts-and-corporate-presentation/. To access the event via phone, please dial +1 (929) 205-6099 for U.S. callers, or +44 (203) 481-5240 for international callers, and reference meeting ID 847 4106 6227 approximately 15 minutes prior to the call. To reserve your place in the live event, please contact Alex Fudukidis via e-mail at a.fudukidis@affimed.com. A replay of the webcast/call will be archived on Affimed’s website for 30 days after the call.

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The study achieved an ORR of 32.4% demonstrating anti-tumor activity with a DOR of 2.3 months and a well-managed safety profile. AFM13 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 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**

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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 trends that may affect the industry or the Company, 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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