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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 6-K**

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**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

**For the month of April, 2022**

**Commission File Number: 001-36619**

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**Affimed N.V.**

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**Im Neuenheimer Feld 582,  
69120 Heidelberg,  
Germany**  
(Address of principal executive offices)

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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):

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## AFFIMED N.V.

On April 8, 2022, Affimed N.V. (Nasdaq: AFMD) (“Affimed,” or the “Company”) issued a press release titled “Affimed Presents Findings from the Dose-escalation Phase of the First-in-human Study of AFM24 in Patients with EGFR-positive Solid Tumors,” announcing data from the dose escalation phase of the phase 1/2a study of AFM24 as monotherapy at AACR. The pharmacokinetic and CD16A receptor occupancy data demonstrated good target engagement at doses of 320 mg and 480 mg and enrollment in the dose escalation has continued at a dose of 720 mg for the purpose of collecting additional data on safety and tolerability. We are enrolling patients in three open label phase 1/2a studies, evaluating the activity of AFM24 as monotherapy (AFM24-101), and in combination with Roche’s anti-PD-L1 checkpoint inhibitor atezolizumab (AFM24-102) as well as in combination with SNK01, NKGen Biotech’s NK cell product (AFM24-103).

On April 10, 2022, the Company issued a press release titled “Affimed Presents Updated Clinical Data from Phase 1/2 Study of AFM13 Precomplexed with Cord Blood-Derived NK Cells at AACR Annual Meeting,” where it provided a data update from the ongoing study of the Company’s lead innate cell engager (ICE®) AFM13 precomplexed with cord blood-derived natural killer (cbNK) cells. AFM13 is currently being investigated at The University of Texas MD Anderson Cancer Center (MDACC) in a phase 1/2 study in patients with CD30-positive relapsed or refractory Hodgkin and non-Hodgkin lymphomas. The investigator-sponsored study is led by Yago Nieto, M.D., Ph.D., professor of Stem Cell Transplantation and Cellular Therapy at MDACC. The study shows a 100% objective response rate (ORR) and an improvement of complete response (CR) rate to 62% at the recommended phase 2 dose (RP2D) in 13 patients after 2 cycles of therapy.

As of the cut-off date, the study had enrolled 22 patients with relapsed or refractory CD30+ Hodgkin and non-Hodgkin lymphoma having received a median of seven prior lines of therapy, of whom 19 were evaluable for response. Thirteen response-evaluable patients were treated at the RP2D, including 12 patients with Hodgkin Lymphoma and one patient with non-Hodgkin Lymphoma. Each treatment cycle consists of lymphodepleting chemotherapy with fludarabine and cyclophosphamide 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.

All 13 patients treated at the recommended phase 2 dose (10<sup>8</sup> NK/Kg) achieved a response by Lyric criteria. Of these 13 patients, 8 patients (62%) demonstrated a CR after two cycles of treatment, which represents an increase from 5 patients (38%) demonstrating CR after one cycle of treatment as previously announced in December 2021.

For the 13 patients treated at the RP2D, median duration of response has not yet been reached. As of the cutoff date, assessment of durability shows:

- Seven patients remain in CR at median follow-up of 6.5 months, including two patients who remain in response after 10 months and two patients who received stem cell transplant and remain in response at 6.5 months
- One patient with a CR experienced disease progression after 7.9 months
- Of the five patients with a PR, one remains in response at 6.3 months and four patients progressed between 2.9 and 4.3 months after initial infusion

The treatment was well tolerated, 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 six infusion-related reactions in 110 infusions (5.4%) of AFM13 alone and no reactions to the cord blood-derived NK cells precomplexed with AFM13.

The trial was originally designed to include up to two cycles. To assess durability beyond two cycles, an amendment has been approved by the U.S. Food and Drug Administration to increase the length of treatment from two up to four cycles, enabling longer follow up of patients.

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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.

Also on April 10, 2022, the Company made available an updated corporate presentation and a presentation regarding AFM13, both of which may be obtained by visiting [www.affimed.com](http://www.affimed.com). The fact that these presentations are being made available should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the presentations is being provided as of April 10, 2022 and the Company does not undertake any obligation to update the presentations in the future nor to update forward-looking statements to reflect subsequent actual results.

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**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 Heidelberg, Germany on April 11, 2022.

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

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<a href="#">Affirmed N.V. Press Release dated April 8, 2022.</a>
99.2	<a href="#">Affirmed N.V. Press Release dated April 10, 2022.</a>

**PRESS RELEASE****Affimed Presents Findings from the Dose-escalation Phase of the First-in-human Study of AFM24 in Patients with EGFR-positive Solid Tumors**

- The recommended phase 2 dose was determined at 480 mg
- AFM24 has demonstrated a well-managed safety profile
- Pharmacodynamic activity was observed at doses of 160 mg and higher
- The maximum tolerated dose was not reached and the dose escalation continues at 720 mg
- For the broad clinical AFM24 program, patients are recruited in three studies, two of which are combination studies, in 7 indications

**Heidelberg, Germany, April 8, 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 data from the dose escalation phase of the phase 1/2a study with the Company’s Innate Cell Engager (ICE®) AFM24 as monotherapy at the Annual Meeting of the American Association of Cancer Research (AACR). A poster will be presented on April 11 during the Phase I Clinical Trials 1 session.

The poster presentation includes data of 29 heavily pretreated patients with a variety of tumors known to express EGFR, who have received AFM24 as weekly infusions across six dose levels from 14 mg to 480 mg. AFM24 demonstrated a well-managed safety profile. The most frequent treatment-emergent adverse events were infusion-related reactions, nausea and headache. Stable disease was observed as best response in 8 of 24 response-evaluable patients.

The pharmacokinetic and CD16A receptor occupancy data demonstrate good target engagement at doses of 320 mg and 480 mg. Pharmacodynamic activity was observed at doses of 160 mg and higher. The recommended phase 2 dose was determined at 480 mg based on safety and tolerability, exposure and CD16A receptor occupancy. The maximum tolerated dose was not reached by the treatment regimen up to 480 mg. Enrollment in the dose escalation has continued at a dose of 720 mg for the purpose of collecting additional data on safety and tolerability.

“Having reached a safe and well-tolerated recommend phase 2 dose with pharmacologic and pharmacodynamic activity is a major milestone for the AFM24 program,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. “This has been important for the initiation of a broad development program assessing the efficacy of AFM24 as monotherapy and in combinations, and we’re planning to provide first updates on the studies in 2022.”

Affimed is enrolling patients in three open label phase 1/2a studies, evaluating the activity of AFM24 as monotherapy (AFM24-101), and in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab (AFM24-102) as well as in combination with SNK01, NKGen Biotech's NK cell product (AFM24-103).

The abstract and poster are electronically accessible for participants of the AACR conference following this link: <https://bit.ly/3ukFMqc>

An update of another ICE®, AFM13, combined with cord blood-derived NK cells in patients with CD30-positive lymphoma will be presented on Sunday, April 10, 1:00 – 3:00 p.m. CST in the session *Clinical Trials of Cellular Immunotherapies*.

#### **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 a monotherapy (AFM24-101) for patients with advanced EGFR-expressing solid malignancies whose disease has progressed after treatment with previous anticancer therapies. The first-in-human Phase 1/2a open-label, non-randomized, multi-center, multiple ascending dose escalation and expansion study and can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) using the identifier NCT04259450. Furthermore, AFM24 is evaluated in a phase 1/2a study in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab (AFM24-102, NCT05109442). Affimed and NKGen Biotech have initiated a Phase 1/2a study, investigating AFM24 in combination with SNK01, NKGen Biotech's NK cell product (AFM24-103, NCT05099549).

#### **About Affimed N.V.**

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to give 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](http://www.affimed.com).

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**PRESS RELEASE****Affimed Presents Updated Clinical Data from Phase 1/2 Study of AFM13 Precomplexed with Cord Blood-Derived NK Cells at AACR Annual Meeting**

- 100% objective response rate and improvement in the rate of complete responses (CR) from 38% to 62% after a second cycle in 13 patients treated at the recommended phase 2 dose (RP2D)
- Patients enrolled were multi-refractory with a median of seven prior lines of treatment; all Hodgkin Lymphoma patients had failed brentuximab vedotin and PD-1 therapy in addition to failing multiple lines of chemotherapy
- Of the eight patients who achieved a CR at the RP2D, seven remain in CR at median follow-up of 6.5 months, including 2 patients who remain in response after 10 months and two who received a consolidation autologous stem cell transplant (SCT)
- Treatment was well tolerated; no instances of cytokine release syndrome, immune effector cell-associated neurotoxicity or graft versus host disease were observed
- Data to be presented by Dr. Yago Nieto of The University of Texas MD Anderson Cancer Center, principal investigator of the study, as an oral presentation at AACR today, April 10, 1:00-3:00 p.m. CST during the Clinical Plenary Session

**Heidelberg, Germany, April 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 study of the Company’s lead innate cell engager (ICE®) AFM13 precomplexed with cord blood-derived natural killer (cbNK) cells. AFM13 is currently being investigated at The University of Texas MD Anderson Cancer Center in a [phase 1/2 study](#) in patients with CD30-positive relapsed or refractory Hodgkin and non-Hodgkin lymphomas. The investigator-sponsored study is led by Yago Nieto, M.D., Ph.D., professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson. The study shows a 100% objective response rate (ORR) and an improvement of complete response (CR) rate to 62% at the recommended phase 2 dose (RP2D) in 13 patients after 2 cycles of therapy. The results will be presented today during the Clinical Plenary Session on cellular immunotherapies at the American Association for Cancer Research (AACR) Annual Meeting 2022 and will also be covered during an AACR press conference this morning.



“The data that we report today are highly encouraging. All patients on this trial were refractory to all available treatment options. Still the combination of AFM13 and precomplexed NK cells resulted in a 100% response rate and a 62% rate of complete responses. We are excited to see a deepening of responses from partial responses to complete responses with a second cycle and have amended the study to allow patients to receive additional cycles, which may further increase the efficacy,” said Dr Andreas Harstrick, Chief Medical Officer at Affimed. “To our knowledge, this is the highest response rate reported so far in Hodgkin Lymphoma patients with treatment refractory disease.”

As of the cut-off date, the study had enrolled 22 patients with relapsed or refractory CD30+ Hodgkin and non-Hodgkin lymphoma having received a median of seven prior lines of therapy, of whom 19 were evaluable for response. Thirteen response-evaluable patients were treated at the RP2D, including 12 patients with Hodgkin Lymphoma and one patient with non-Hodgkin Lymphoma. Each treatment cycle consists of lymphodepleting chemotherapy with fludarabine and cyclophosphamide 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.

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“A year ago, we were struck with hopeful optimism when the first four patients in the study all showed a response. Now, we are again presenting data at AACR and the results not only hold strong in a larger patient population but also show an increasing number of CRs with early but encouraging durability,” commented Dr. Adi Hoess, Chief Executive Officer at Affimed. “These ongoing successes with AFM13 represent an important milestone for Affimed and could mark a turning point in the innate immuno-oncology space, potentially setting the stage for expanding this approach to additional cancer indications. Our goal is to leverage the distinct features of our ROCK® platform to generate best-in-class ICE® molecules that drive effective innate immune cell activation for the benefit of broad patient populations, addressing hematologic and solid tumor malignancies.”

The trial was originally designed to include up to two cycles. To assess durability beyond two cycles, an amendment has been approved by the U.S. Food and Drug Administration to increase the length of treatment from two up to four cycles, enabling longer follow up of patients.

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. AFM13 is also being investigated as a monotherapy and can bind the patient’s own NK cells, thus boosting their existing capacity to fight cancerous cells. When precomplexed with AFM13, NK cells exhibit immediate expansion in the patient’s circulation which persists for at least two weeks.

### **Oral presentation details**

**Title:** Innate cell engager (ICE®) AFM13 combined with preactivated and expanded cord blood (CB)-derived NK cells for patients with refractory/relapsed CD30+ lymphoma

**Presentation:** CT003

**Session:** Clinical Trials of Cellular Immunotherapies, Sunday, April 10, 1:00 – 3:00 p.m. CST

### **About the 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 pre-complexed NK cells, with patients receiving  $1 \times 10^6$  NK cells/kg in Cohort 1;  $1 \times 10^7$  NK cells/kg in Cohort 2; and  $1 \times 10^8$  NK cells/kg in Cohort 3. The trial is designed to explore safety and activity and determine the recommended Phase 2 dose. In each cohort, the dose of the pre-complexed NK cells with AFM13 is to be followed by weekly doses of 200 mg AFM13 monotherapy for three weeks, with each patient evaluated for dose-limiting toxicities and responses on day 28.

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 \(NCT04074746\)](http://www.clinicaltrials.gov/NCT04074746).

## **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 or transformed mycosis fungoides (REDIRECT). Additional details can be found at [www.clinicaltrials.gov](http://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](http://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 our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the potential of AFM13, AFM24, AFM28 and our other product candidates, the value of our ROCK® platform, our ongoing and planned preclinical development and clinical trials, our collaborations and development of our products in combination with other therapies, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, our collaboration activities, our ability to develop commercial functions, clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies, the industry in which we operate, the trends that may affect the industry or us, impacts of the COVID-19 pandemic, the benefits to Affimed of orphan drug designation and the risks, uncertainties and other 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 we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.

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