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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 January, 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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## INCORPORATION BY REFERENCE

On January 6, 2022, Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced that it has completed enrollment in the REDIRECT study and provided a business update.

The text above shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-227933), Form F-3 (Registration Number 333-251648), Form F-3 (Registration Number 333-260946) and Form S-8 (Registration Numbers 333-198812) of Affimed N.V. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. 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 it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

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EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<a href="#">Affirmed N.V. Press Release dated January 6, 2022</a>

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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 January 6, 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

**PRESS RELEASE****Affimed Announces Completion of Enrollment in REDIRECT, the Registration-Directed Study of AFM13 in PTCL, and Provides Business Update**

- Enrollment of REDIRECT study (AFM13-202) is completed; topline clinical readout expected in 2H 2022
- FDA approves protocol amendment to allow for (i) enrollment of up to 40 patients at the highest dose level, and (ii) treatment of patients with more than two cycles in the investigator sponsored trial of cord blood-derived natural killer (cbNK) cells pre-complexed with AFM13 (AFM13-104)
- Broad development strategy launched for AFM24 – enrollment initiated in three studies addressing major EGFR-expressing solid tumor indications including non-small cell lung and colorectal cancer
- For AFM28 a first in human study initiation is planned for second half of 2022
- Cash position provides funding into 2H 2023

**Heidelberg, Germany, January 6, 2022** – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced today that it has completed enrollment in the REDIRECT study and provided a business update.

REDIRECT, also known as AFM13-202 (NCT04101331), is a registration-directed phase 2 open-label, multicenter, global study investigating the efficacy and safety of AFM13 monotherapy in patients with relapsed or refractory CD30-positive peripheral T-cell lymphoma (PTCL). Affimed expects to report topline data from the REDIRECT study in the second half of 2022.

“Completing the enrollment in the registration directed trial of AFM13, our lead innate cell engager, is an important milestone for us and reflects our ability to progress and advance our clinical pipeline. The high response rates reported in December 2021 from our combination study with natural killer cells in Hodgkin Lymphoma represent a marked expansion of the business opportunity of AFM13. We are looking forward to solidifying the opportunity for AFM13 when we report additional data this year,” said Dr. Adi Hoess, Chief Executive Officer of Affimed. “Data generated from multiple AFM13 trials provide us with confidence in the development strategy for AFM24 and AFM28, for which we expect to provide additional updates during 2022.”

The REDIRECT trial protocol, in addition to the registration relevant cohorts A and B in PTCL, includes an arm to investigate AFM13 therapy in patients with Transformed Mycosis Fungoides (TMF), which is exploratory and not relevant to the potential consideration for accelerated

approval. As previously announced, recruitment of TMF patients was paused due to the COVID-19 pandemic. At this time, Affimed has decided not to pursue the investigation of AFM13 therapy in patients with TMF due to the continuing impact of the COVID-19 pandemic and the completion of enrollment of the registration-directed portion of the trial.

### **Update on Other Programs**

#### **AFM13 (CD30/CD16A ICE®)**

The United States Food and Drug Administration (FDA) has approved a proposed amendment to the AFM13-104 trial protocol to increase the patient population treated at the recommended phase 2 dose (RP2D) to 40 CD30-positive lymphoma patients, including both Hodgkin Lymphoma (HL) patients and non-Hodgkin Lymphoma (NHL) patients, and allow for the treatment of patients with more than the two cycles of therapy, at the investigator's discretion. With the approval of the protocol amendment, The University of Texas MD Anderson Cancer Center (MDACC) has initiated enrollment of patients into the phase 2 portion of the trial, triggering an undisclosed milestone payment to MDACC which Affimed expects to make during the first quarter of 2022.

AFM13-104 is an investigator sponsored trial (IST) at MDACC investigating the treatment of CD30-positive lymphoma patients with cbNK cells, pre-complexed with AFM13. In December 2021, Affimed reported updated data from the trial, including a 100% objective response rate after a single cycle of treatment for the 13 patients treated at the RP2D of  $1 \times 10^8$  cbNK cells precomplexed with AFM13 followed by 3 weekly infusions of AFM13. All three patients treated at the RP2D with at least 6 months of follow-up remained in complete response as of the cutoff date.

#### **AFM24 (EGFR/CD16A ICE®)**

During the fourth quarter of 2021, Affimed announced that it had identified the RP2D for AFM24 monotherapy of 480 mg weekly in patients with EGFR-expressing solid tumors. With the achievement of this milestone, Affimed has now embarked on a broad development strategy for AFM24, which includes the initiation of three studies investigating various EGFR-expressing solid tumor indications.

Affimed has initiated enrollment in the expansion phase of the monotherapy AFM24 trial at the RP2D. The trial includes patients with renal cell carcinoma (clear cell), non-small cell lung cancer (EGFR-mutant) and colorectal cancer.

Affimed also initiated enrollment in two separate phase 1/2a combination studies. The first is investigating the combination of AFM24 with SNK01 (ex vivo expanded and activated autologous NK cell therapy from NKGen Biotech) to treat patients with non-small cell lung cancer (NSCLC, EGFR-wildtype), squamous cell carcinoma of the head and neck, and colorectal cancer. The second study will investigate the combination of AFM24 with Roche's atezolizumab, an anti-PD-L1 checkpoint inhibitor to treat patients with non-small cell lung cancer (EGFR-wildtype), gastric and gastroesophageal junction adenocarcinoma and pancreatic/hepatocellular/biliary tract cancer.

Affimed expects to report data updates from the AFM24 trials during 2022.

## **AFM28 (CD123/CD16A ICE®)**

AFM28 is currently being prepared for clinical evaluation with an IND filing planned for the first half of 2022 and a first in human study is planned to start in second half of 2022. Initial preclinical data for AFM28 was presented at the 63rd American Society of Hematology Annual Meeting (ASH) in December 2021, demonstrating antibody-dependent cell-mediated cytotoxicity (ADCC) even at low CD123 expression which was more pronounced compared to conventional anti-CD123 antibodies. In addition, AFM28 showed a 100-fold more potent NK cell activation in an ex vivo analysis, compared to Fc-enhanced IgG1 antibodies. Further, AFM28 was well tolerated and showed pharmacodynamic activity in cynomolgus monkeys.

### **Preliminary Cash Balance and Cash Runway Guidance**

As of December 31, 2021, Affimed's preliminary unaudited cash and cash equivalents were approximately €197 million. The cash balance includes €7.4 million of net proceeds received from the second tranche of Affimed's loan agreement with Silicon Valley Bank, which was drawn in December 2021. Based on its current operating plan and assumptions, Affimed anticipates that its cash and cash equivalents will support operations into the second half of 2023.

### **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).

### **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,

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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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