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 January, 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 January 9, 2023, Affimed N.V. (Nasdaq: AFMD) ("Affimed," or the "Company") issued a press release titled "Affimed Reports on Corporate Progress and Provides Regulatory Update for AFM13" announcing that the U.S. Food and Drug Administration has issued a written response to the Company's pre-investigational new drug ("IND") meeting request for the AFM13 and Artiva Biotherapeutics, Inc. AB-101 co-administered combination therapy in relapsed/refractory Hodgkin lymphoma and the exploratory arm evaluating the combination in r/r CD30-positive peripheral T-cell lymphoma. Based on the written response, Affimed remains on track to submit an IND in the first half of 2023 and, subject to FDA clearance of the IND, to initiate a clinical study during 2023.

The press release also provided updates regarding Affimed's other clinical stage programs:

- AFM24-101: Affimed continues to enroll patients in the expansion phase of the AFM24 monotherapy study at the recommended phase 2 dose. The expansion cohorts include patients with renal cell carcinoma (clear cell), non-small cell lung cancer (EGFR mutant) and colorectal cancer.
- AFM24-102: Enrollment is completed in the 480 mg dose escalation cohort of the phase 1/2a combination study of AFM24 with the anti-PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in patients with advanced epidermal growth factor receptor-expressing solid tumors. AFM24-102 includes patients with non-small cell lung cancer (EGFR wildtype), gastric and gastroesophageal junction adenocarcinoma and pancreatic/hepatocellular/biliary tract cancer. No dose-limiting toxicities (DLTs) have been observed thus far in the dose escalation.

  Data from the first cohort (4 patients at 160 mg dose) of the phase 1 dose escalation study presented at the annual meeting of the Society for Immunotherapy of Cancer in November 2022 showed that clinical activity was observed in two patients. A patient with gastric cancer and skin metastases who had rapidly progressed following four prior lines of therapy, including a PD-1 inhibitor, achieved a partial response. A second patient with pancreatic adenocarcinoma showed stable disease beyond four months. Patients being enrolled in the study are required to have progressed or relapsed on standard of care therapies.
- AFM24-103: In the phase 1/2a combination study of AFM24 with SNK01, NKGen Biotech's ex vivo expanded and activated autologous NK cell therapy, enrollment has been completed in the dose cohort of 480 mg AFM24 weekly, with no DLTs observed to date.
- AFM28 (CD123/CD16A): In December 2022, clinical trial applications were cleared in France and Spain.

A copy of the press release is attached hereto as Exhibit 99.1 and is 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.

FORWARD-LOOKING STATEMENTS

This report 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 report 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.

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: January 9, 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 January 9, 2023.

PRESS RELEASE

Affimed Reports on Corporate Progress and Provides Regulatory Update for AFM13

- AFM13 combination with Artiva's AB-101 NK cells: Received written feedback to pre-investigational new drug (IND) meeting request which supports plan for IND filing in H1 2023 and initiation of clinical study during 2023
- AFM24: Data updates from the three AFM24 ongoing studies are expected at scientific conferences in Q2/Q3 2023
- AFM28: Clinical trial application (CTA) cleared in France and Spain with additional filings in European countries pending; initiation of phase 1 study is expected in Q2 2023
- Anticipated cash runway into 2025: as of December 31, 2022, preliminary unaudited cash and cash equivalents were approximately €190 million

Heidelberg, Germany, January 9, 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 that the U.S. Food and Drug Administration (FDA) has issued a written response to the Company's pre-IND meeting request for the AFM13 and Artiva Biotherapeutics, Inc. ("Artiva")'s AB-101 co-administered combination therapy in relapsed/refractory (r/r) Hodgkin lymphoma (HL) and the exploratory arm evaluating the combination in r/r CD30-positive peripheral T-cell lymphoma (PTCL). Based on the written response, Affimed remains on track to submit an IND in the first half of 2023 and, subject to FDA clearance of the IND, to initiate a clinical study during 2023.

"We remain excited about the clinical and commercial potential of the AFM13/AB-101 combination therapy for CD30-positive HL and PTCL patients and look forward to initiating clinical development during 2023," said Dr. Adi Hoess, CEO of Affimed. "We believe there is significant unmet need to help patients in these difficult cancer indications with limited treatment options and continue to make progress across our pipeline. We are looking forward to sharing key clinical milestones in 2023 and beyond."

In November 2022, Affimed announced that it had entered into a strategic partnership to jointly develop, manufacture and commercialize a combination therapy comprised of Affimed's Innate Cell Engager (ICE®) AFM13 and Artiva's cord blood-derived, cryopreserved off-the-shelf allogeneic NK cell product candidate, AB-101, to accelerate clinical development and address the high unmet need of CD30-positive lymphoma patients.

Other Clinical Stage Program Updates

AFM24 (EGFR/CD16A)

- Affimed expects to report data from all three ongoing AFM24 studies at scientific conferences in Q2/Q3 2023.
- AFM24-101: Affimed continues to enroll patients in the expansion phase of the AFM24 monotherapy study at the RP2D. The expansion cohorts include patients with renal cell carcinoma (clear cell), non-small cell lung cancer (EGFR mutant) and colorectal cancer.
- AFM24-102: Enrollment is completed in the 480 mg dose escalation cohort of the phase 1/2a combination study of AFM24 with the anti-PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in patients with advanced epidermal growth factor receptor-expressing solid tumors. AFM24-102 includes patients with non-small cell lung cancer (EGFR wildtype), gastric and gastroesophageal junction adenocarcinoma and pancreatic/hepatocellular/biliary tract cancer. No dose-limiting toxicities (DLTs) have been observed thus far in the dose escalation. Expansion cohorts are expected to begin enrollment in Q1 2023.

  Data from the first cohort (4 patients at 160 mg dose) of the phase 1 dose escalation study presented at the annual meeting of the Society for Immunotherapy of Cancer (SITC) in November 2022 showed that clinical activity was observed in two patients. A patient with gastric cancer and skin metastases who had rapidly progressed following four prior lines of therapy, including a PD-1 inhibitor, achieved a partial response. A second patient with pancreatic adenocarcinoma showed stable disease beyond four months. Patients being enrolled in the study are required to have progressed or relapsed on standard of care therapies.
- AFM24-103: In the phase 1/2a combination study of AFM24 with SNK01, NKGen Biotech's *ex vivo* expanded and activated autologous NK cell therapy, enrollment has been completed in the dose cohort of 480 mg AFM24 weekly, with no DLTs observed to date.

  AFM24-103 is focused on the treatment of patients with non-small cell lung cancer (NSCLC, EGFR-wildtype), squamous cell carcinoma of the head and neck, and colorectal cancer.

AFM28 (CD123/CD16A)

Affimed's AFM28 ICE® targets CD16A on NK cells and macrophages, and CD123 on leukemic blasts and leukemic stem cells that are prevalent in acute myeloid leukemia (AML).

In December 2022, CTAs were cleared in France and Spain, and the Company expects to initiate a phase 1 clinical study in Q2 2023.

Financial Update

As of December 31, 2022, preliminary unaudited cash and cash equivalents were approximately €190 million, with an anticipated cash runway into 2025.

Partnerships and Collaborations

Partnered programs with Genentech and Affivant (a Roivant company) continue to progress. Affimed is eligible for additional proceeds including pre-clinical milestones as well as milestones based on early regulatory achievements. Affivant expects to file an IND for AFVT-2101 (formerly AFM32) in the first half of 2023.

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.

About Artiva

Artiva's mission is to deliver highly effective, off-the-shelf, allogeneic NK cell-based therapies utilizing our Manufacturing-First approach, that are safe and accessible to cancer patients. Artiva's pipeline includes AB-101, an ADCC enhancer NK-cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers. Artiva is currently advancing a Phase 1/2 clinical trial of AB-101 in combination with rituximab for the treatment of relapsed or refractory B-cell lymphomas. Artiva's pipeline also includes AB-201, an anti-HER2 CAR-NK cell therapy candidate for the treatment of HER2-overexpressing tumors, such as breast, gastric, and bladder cancers, and for which an IND has been allowed by FDA, and a pipeline of CAR-NK candidates targeting both solid and hematopoietic cancers. Artiva is headquartered in San Diego. For more information, please 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 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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