# 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, 2017

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):

# **INCORPORATION BY REFERENCE**

Exhibit 99 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-207235) and Form S-8 (Registration Number 333-198812) of Affimed N.V. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

# 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, January 11, 2017.

AFFIMED N.V.

<u>By:</u> /s/ Adi Hoess

Name: Adi Hoess Title: Chief Executive Officer

<u>By:</u> /s/ Florian Fischer

Name: Florian Fischer Title: Chief Financial Officer

ExhibitDescription of Exhibit99Affimed Provides Update on NK-Cell Immuno-Oncology Platform



# FOR IMMEDIATE RELEASE

# Affimed Provides Update on NK-Cell Immuno-Oncology Platform

Heidelberg, Germany January 11, 2017 - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies, today provided an update on its NK-cell engager platform.

"In 2016, we have significantly expanded our activities to optimize the elimination of malignant cells through NK-cell engagement, namely advancing our Phase 1b clinical trial of AFM13 in combination with Merck's Keytruda and broadening our approach to include the combination of our NK-cell engagers with adoptive transfer of activated NK-cells developed at MD Anderson," said Adi Hoess, Ph.D., CEO of Affimed.

"We further progressed our preclinical NK-cell engager pipeline with our EGFR-targeting solid tumor candidate AFM24 and BCMA-targeting multiple myeloma candidate AFM26," added Martin Treder, Ph.D., CSO of Affimed. "Due to their high affinity and specificity to CD16A, our molecules offer a novel mechanism of action for NK-cell and macrophage engagement and avoid competition by high IgG serum levels, which currently limits the efficacy of monoclonal antibody-based treatments. In addition, we have gathered important insights into NK-cell biology in various preclinical studies which will allow us to explore further treatment options, for example combining our NK-cell engagers with cytokines such as IL-15 or IL-2."

#### Leadership position in activating innate and adaptive immunity through engaging NK-cells and macrophages

Focusing its efforts on antibodies specifically binding NK-cells through CD16A, a dominant activating receptor on innate immune cells, Affimed has built a clinical and preclinical pipeline of NK-cell-engaging bispecific antibodies (TandAbs<sup>®</sup>) designed to activate both innate and adaptive immunity. Compared to a variety of T-cell-engaging technologies, Affimed's NK-cell engagers appear to have a better safety profile and have the potential to achieve more potent and deeper immune responses through enhancing crosstalk of innate to adaptive immunity. Building on its leadership in the NK-cell space, Affimed is also developing tetravalent, bispecific alternative antibody formats (AAFs) for NK-cell engagement offering varying PK/PD profiles relevant to certain diseases.

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#### Product candidate AFM13: The most advanced NK-cell engager in clinical development

The Company's lead product candidate, AFM13 targeting CD16A on NK-cells and CD30 on tumor cells, is the most advanced NK-cell engager in the clinic. Its development is focused on combination therapy and supported by The Leukemia & Lymphoma Society (LLS).

AFM13 is differentiated from monoclonal antibodies as it displays a 1000-fold higher binding affinity to CD16A, shows very limited competition for NK-cell binding with circulating IgG, as well as higher potency compared to full-length CD30 antibodies. Safety and clinical/pharmacodynamic activity in heavily pretreated Hodgkin lymphoma (HL) patients was established in a Phase 1 study and based on its favorable safety profile and preclinical data, AFM13 is currently under investigation as a combination therapy.

#### NK-cell engagers in combination therapy

Combination therapies have demonstrated improved outcomes for cancer patients and are widely pursued to maximize efficacy of immunotherapeutic approaches. Further broadening the therapeutic opportunities for its NK-cell engagers, Affimed is investigating AFM13 in several combination therapies.

It is becoming increasingly clear that modulation of immune effectors or the immunosuppressive environment result in higher overall response rates and extended durability of response. *In vivo* studies in a patient-derived xenograft (PDX) model have shown that combining AFM13 with checkpoint inhibitors leads to synergistic efficacy of AFM13 when combined with anti-PD-1, likely attributable to the combination of both agents inducing crosstalk between innate and adaptive immunity. Consequently, AFM13 is being investigated with Merck's anti-PD1 antibody Keytruda in a Phase 1b clinical trial.

Currently in early clinical development in a number of hematological malignancies, the adoptive transfer of activated NK-cells provides a strong combination rationale with Affimed's NK-cell platform to better exploit the therapeutic power of NK-cells. For this, the Company has entered into an exclusive strategic clinical development and commercialization collaboration with MD Anderson Cancer Center (MDACC), in which Affimed intends to investigate AFM13 preclinically and clinically in combination with MDACC's proprietary NK-cell product in HL. Beyond HL, this approach has potential applications in further medically underserved indications such as multiple myeloma or acute myeloid leukemia.

Cytokines such as IL-2 or IL-15 boost NK-cell activity and are tested clinically in a variety of cancers. In recent preclinical studies, Affimed demonstrated that AFM13 induced the upregulation of specific interleukin receptors on NK-cells and the subsequent addition of IL-2 or IL-15 had a synergistic effect on AFM13-mediated NK-cell expansion. Hence, the combination of NK-cell engagers with such cytokines may be clinically useful to deepen responses.

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# **Ongoing Clinical Studies**

### AFM13 in combination with Merck's PD-1 inhibitor Keytruda®

Affimed is developing AFM13 in combination with the anti-PD-1 antibody Keytruda (pembrolizumab) in relapsed/refractory HL in collaboration with Merck, with Affimed being the study's sole sponsor and Merck supplying Affimed with Keytruda for the trial. The Company has initiated a Phase 1b dose-escalation combination study and safety was determined in the first dose cohort, in which three patients were treated with Keytruda at active dose and AFM13 at 0.5 mg/kg, a level below its active dose when used as single agent. At restaging after 3 months, 2 out of 3 patients had a partial response, which is in line with expectations. With the second dose cohort now fully recruited, Affimed anticipates to provide a further update on the study in the first half of 2017.

#### AFM13 Phase 2a monotherapy in HL

In Affimed's investigator-sponsored Phase 2a monotherapy of AFM13 in HL, the Company and the study's sponsor, the German Hodgkin Study Group (GHSG), have revised the overall study design in order to adapt to the changing treatment landscape, namely the earlier availability of anti PD-1 antibodies. The study will now include HL patients relapsed or refractory to treatment with both brentuximab vedotin (Adcetris<sup>®</sup>) and anti-PD-1. The study is expected to begin recruiting under the new study design in the first quarter of 2017 and Affimed anticipates providing an update on the study in the second half of 2017.

### **Preclinical Product Candidates**

#### AFM24 and AFM24+ (targeting EGFR/CD16A)

Affimed is developing its first-in-class NK-cell engager AFM24 to address the critical unmet need to effectively treat epidermal growth factor receptor (EGFR)-expressing solid tumors such as lung, head & neck and colon cancers,. The molecule has been shown to be well differentiated from other EGFR-targeting therapies such as cetuximab through its more potent cytotoxic activity *in vitro* and *in vivo* and being able to kill tumor cells when they express mutated proto-oncogene *RAS*, a negative predictive biomarker for EGFR-targeting monoclonal antibodies. In contrast to cetuximab, AFM24 shows very limited competition of NK-cell-binding by circulating IgG. Together with the synergy shown for combining an NK-cell engager (AFM13) and an anti-PD1 antibody in *in vivo* models, the recent approval of anti-PD-1/anti-PD-L1 antibodies in non-small lung cancer (NSCLC) and squamous cell carcinoma of the head and neck (SCCHN), offer a therapeutic rationale for a combination with AFM24 in these indications. IND-enabling toxicology studies for AFM24 are progressing. AFM24+, which is based on AFMD's newly developed AAFs, is a tetravalent bispecific antibody offering a different PK/PD profile. Affimed expects to provide a further update on these programs in the first half of 2017.

#### AFM26 and AFM26+ (targeting BCMA/CD16A)

Multiple myeloma (MM) is characterized by very high serum levels of M-protein, clonal immunoglobulins produced in excess by malignant plasma cells in patients. M-protein strongly impairs ADCC of conventional monoclonal antibodies and MM patients currently suffer from very high relapse rates, leaving the need for improved and durable therapies. Affimed is developing AFM26, a TandAb targeting B-cell maturation antigen (BCMA), a validated target in MM. AFM26-mediated NK-cell-binding has been shown to be largely unaffected by circulating IgG, indicating the potential for NK-cell activation in the presence of M-protein, thus introducing a novel mechanism of action. Comparable to other NK-cell engagers AFM26 is characterized by its high affinity to tumor cells and NK-cells, prolonged cell retention time, as well as high *in vitro* potency towards BCMA-expressing myeloma cell lines. AFM26+, which is based on AFMD's newly developed AAFs, is a tetravalent bispecific antibody with a different PK/PD profile. Affimed expects to provide a first update on these programs in the first half of 2017.

#### **About Affimed's Products**

Affimed develops bi- and trispecific immune cell-engaging antibodies with a tetravalent architecture characterized by four binding domains (TandAbs, AAFs, TriFlex). Affimed's products are designed to substantially increase the efficacy, specificity and/or to extend the therapeutic window of current therapeutics. Binding to targets on both the immune and the tumor cell, they redirect immune cells and establish a bridge between either NK-cells or T-cells and tumor cells, triggering a signal cascade that leads to the destruction of tumor cells. Their appropriate safety profile makes them suitable for development in mono- and combination therapy. In clinical studies, Affimed's TandAb products have already demonstrated promising signs of therapeutic activity in patients.

#### About Affimed N.V.

Affimed (Nasdaq: AFMD) engineers targeted immunotherapies, seeking to cure patients by harnessing the power of innate and adaptive immunity (NK- and T-cells). We are developing single and combination therapies to treat cancers and other life-threatening diseases. For more information please visit www.affimed.com.

#### AFFIMED 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, 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, expectations regarding 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 and the risks uncertainties and other factors described under the heading "Risk Factors" in Affimed's filings with the Securities and Exchange Commission. 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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