# 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 April, 2021
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): $\Box$
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 April 15, 2021, Affimed N.V. issued a press release, a copy of which is attached hereto as Exhibit 99.1.

# **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, April 15, 2021.

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

Exhibit Description of Exhibit

99.1\* Affimed N.V. Press Release dated April 15, 2021.

\* 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.



#### PRESS RELEASE

# Affimed Reports 2020 Financial Results and

# **Highlights Recent Operational Progress**

- AFM13 monotherapy: Reported positive data from the preplanned interim analysis for the registration-directed trial in PTCL
- AFM13 combination with NK cells: Announced 100% objective response rate in four response evaluable patients, including 2 complete responses
- AFM24 monotherapy: AFM24 (phase 1/2a study) completed cohort 4 and is enrolling and treating patients in cohort 5; expansion cohorts expected to start in the second half of 2021
- AFM24 combination with NK cells: IND application cleared by the FDA for the combination of AFM24 with NKGen Biotech's SNK-01 NK autologous cell therapy
- AFM24 combination with anti PD-L1 antibody: Established a collaboration with Roche to clinically explore the combination of AFM24 with atezolizumab (Tecentriq®)
- · Made continued progress in advancing and forming partnerships with Genentech and Roivant, which triggered payments to Affimed
- Pro forma cash and cash equivalents as of December 31, 2020 were approximately €244.5 million (inclusive of Q1 equity offering and loan proceeds) with anticipated cash runway into the second half of 2023
- Conference call and webcast scheduled for April 15, 2021 at 8:30 a.m. EDT

**Heidelberg, Germany, April 15, 2021** – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, today reported financial results for the year ended December 31, 2020 and provided an update on clinical and corporate progress.

"2020 was an important year for Affimed. We continued to build on the strong foundation of our scientific discoveries and made significant progress across all our programs. We broadened our clinical pipeline, added new collaborations, built a strong balance sheet, appointed key senior management executives and ensured that our programs stayed on track through the global pandemic," said Dr. Adi Hoess, CEO of Affimed. "We entered 2021 with strong momentum, and the recently announced positive outcome of our interim futility analysis for our registration directed study of AFM13 as monotherapy in PTCL patients, and initial data from the trial investigating AFM13 pre-complexed natural killer cells in Hodgkin lymphoma patients provide further validation for our three-pronged development strategy. As we look ahead into 2021, we anticipate numerous additional updates as we advance our programs."

#### **Clinical Stage Program Updates**

### **Three-pronged Development Strategy**

Based on preclinical and clinical data, Affimed is pursuing development of its innate cell engagers (ICE®) as monotherapy, and in combination with adoptive NK cell transfer and PD-1/PD-L1 checkpoint inhibitors.

# AFM13 (CD30/CD16A)

- In March 2021, Affimed reported positive results from the preplanned interim futility analysis for AFM13-202, its phase 2 registration-directed study of AFM13 (CD16A/CD30) as monotherapy in patients with relapsed or refractory CD30-positive peripheral T-cell lymphoma (PTCL). The futility analysis demonstrated that the response rate in Cohort A achieved the predefined threshold for continuation of the study. The response rate in Cohort B was sufficiently comparable to allow merging of both cohorts into a single cohort for all patients with CD30 >1%, per the study protocol. Evidence of anti-tumor response was observed in both cohorts with complete and partial responses. The trial will continue by combining the high- and low-CD30 expressing cohorts into one.
- In April 2021, Affimed reported positive initial clinical data from the investigator sponsored trial (IST) at The University of Texas MD Anderson Cancer Center evaluating increasing doses of cord-blood derived NK cells pre-complexed with AFM13 (CD16A/CD30) followed by three weekly infusions of AFM13 monotherapy in patients with recurrent or refractory CD30 positive lymphomas. As of March 31, 2021, all four response evaluable patients, including three patients in cohort 1 (1x10<sup>6</sup> AFM13-cbNK/kg) and one patient in cohort 2 (1x10<sup>7</sup> AFM13-cbNK/kg), have achieved an objective response, including two complete responses, according to investigator assessments by Lymphoma Response to Immunomodulatory Therapy Criteria (LYRIC). All four patients had relapsed / refractory Hodgkin lymphoma and were heavily pretreated, with between four and 14 previous lines of therapy which in all cases included brentuximab vedotin (Adcetris®) and anti-PD1 antibodies.

# AFM24 (EGFR/CD16A)

• AFM24-101, the phase 1/2a clinical trial of AFM24, the EGFR/CD16A targeted ICE® for patients with EGFR-expressing solid tumors, completed dose cohort 4 (160 mg) and patients are currently being enrolled and treated in dose cohort 5 (320 mg). Affimed expects to provide an update on the dose escalation and initiate the dose expansion cohorts during 2021.

- An investigational new drug (IND) application was cleared by the U.S. Food and Drug Administration to investigate the combination of AFM24 with NKGen Biotech's (formerly known as NKMax America) autologous NK cell therapy, SNK01, in a first-in-human proof of concept (POC) trial in patients with EGFR-expressing tumors. Affimed expects to initiate the study in the second half of 2021.
- Affimed entered into a clinical collaboration with Roche for a phase 1/2a study evaluating AFM24 in combination with the PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in EGFR-expressing solid tumors. The phase 1 portion of the study will establish a dosing regimen and assess safety for the combination; in the subsequent phase 2a portion of the study, the clinical activity of the combination will be evaluated in specific tumor types. Affimed expects to initiate the study in the second half of 2021.
- Preclinical data was presented at AACR 2021 showing the potential of AFM24 as monotherapy and in combination with NK cells. As monotherapy, AFM24 induces tumor cell killing independent of KRAS mutations; and, in combination with adoptive NK cells, it leads to AFM24 dose-dependent tumor regression.

### **Preclinical and Partnered Programs**

- AFM28 progressed further in IND-enabling studies and Affimed expects an IND application will be filed in the first half of 2022.
- In November 2020, Affimed entered into a licensing and strategic collaboration agreement with Roivant Sciences and granted Roivant a license to AFM32 with options for additional ICE® molecules against targets not included in Affimed's current pipeline. AFM32 will be investigated in solid tumors.
- In August 2020, Affimed announced that Genentech's RO7297089, a CD16A/BCMA targeting ICE®, is actively recruiting patients into a first-in-human phase 1 trial resulting in the achievement of a milestone payment under the terms of the collaboration.
- Affimed entered a collaboration with Artiva Biotherapeutics to assess feasibility and activity of pre-manufactured, co-vialed, cryopreserved, off-the-shelf NK cell combination therapeutics. The R&D collaboration is assessing the feasibility and preclinical activity of combinations of Artiva's allogeneic NK cell product AB-101 and Affimed's ICE® molecules, building on earlier preclinical studies demonstrating synergistic cytotoxic activity.

# **Other Corporate Updates**

- In January 2021, Affimed completed a \$115 million underwritten public offering to accelerate and expand the development and manufacturing of its clinical and preclinical ICE® molecules.
- In January 2021, Affimed entered into a financing agreement with Silicon Valley Bank for up to €25 million in term loans, with €10 million available at closing.

# Full Year 2020 Financial Highlights

As of December 31, 2020, cash, cash equivalents and current financial assets totaled €146.9 million compared to €104.1 million on December 31, 2019. The pro forma cash position as of December 31, 2020, including net proceeds from the January 2021 underwritten public offering and the first tranche of the Silicon Valley Bank loan, would be approximately €244.5 million.

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.

Net cash used in operating activities for the year ended December 31, 2020 amounted to €19.4 million compared to €29.1 million for the year ended December 31, 2019. The amount received in 2020 includes an initial upfront payment and committed funding of €33.3 million (US\$ 40 million) from the Roivant collaboration.

Total revenue for the year ended December 31, 2020 was €28.4 million compared with €21.4 million for the year ended December 31, 2019. Revenue for 2020 and 2019 predominantly relate to the Genentech collaboration. Collaboration revenue for the year ended December 31, 2020 amounted to €27.8 million, with €26.2 million from the Genentech collaboration and €1.4 million from the Roivant collaboration. Collaboration revenue of €19.7 million for the year ended December 31, 2019 was from the Genentech collaboration.

Research and development expenses for 2020 increased 14.2% from €43.8 million in the year ended December 31, 2019 to €50.0 million in the year ended December 31, 2020, due to higher expenses for AFM24 and our other projects and infrastructure investments.

General and administrative expenses increased 33.6% from €10.3 million in the year ended December 31, 2019 to €13.7 million in the year ended December 31, 2020. In 2020, general and administrative expenses were largely comprised of personnel expenses of €6.3 million and legal, consulting and audit costs of €5.6 million.

Finance costs for the year ended December 31, 2020 were €6.6 million, compared to finance income of €15 thousand for the year ended December 31, 2019. Finance costs for the year ended December 31, 2020 were largely comprised of foreign exchange losses related to assets denominated in U.S. dollars as a result of the weakening of the U.S. dollar compared to the Euro during the year.

Net loss for the year ended December 31, 2020 was €41.4 million, or €0.50 per common share compared with a net loss of €32.4 million, or €0.50 per common share, for the year ended December 31, 2019.

The weighted number of common shares outstanding for the year ended December 31, 2020 was 83.5 million.

Additional information regarding these results is included in the notes to the consolidated financial statements as of December 31, 2020 and "Item 5. Operating and Financial Review and Prospects," which will be included in Affimed's Annual Report on Form 20-F as filed with the U.S. Securities and Exchange Commission (SEC).

#### Note on International Financial Reporting Standards (IFRS)

Affimed prepares and reports consolidated financial statements and financial information in accordance with IFRS as issued by the International Accounting Standards Board. None of the financial statements were prepared in accordance with Generally Accepted Accounting Principles in the United States. Affimed maintains its books and records in Euro.

#### **Conference Call and Webcast Information**

Affimed will host a conference call and webcast today, April 15, 2021 at 8:30 a.m. EDT to discuss fourth quarter 2020 financial results and recent corporate developments. The conference call will be available via phone and webcast.

To access the call, please dial +1 (646) 741-3167 for U.S. callers, or +44 (0) 2071 928338 for international callers, and reference passcode 4271307 approximately 15 minutes prior to the call.

A live audio webcast of the conference call will be available in the "Webcasts" section on the "Investors" page of the Affimed website at <a href="https://www.affimed.com/investors/webcasts">https://www.affimed.com/investors/webcasts</a> cp/. A replay of the webcast will be accessible at the same link for 30 days following the call.

#### **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: <a href="https://www.affimed.com">www.affimed.com</a>.

# **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, 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.

# **Investor Relations Contact**

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# Consolidated statements of comprehensive income / (loss) (in ${\mathfrak C}$ thousand)

	2020	2019	2018
Revenue	28,360	21,391	23,735
Other income - net	626	290	1,515
Research and development expenses	(49,989)	(43,791)	(35,148)
General and administrative expenses	(13,715)	(10,266)	(9,638)
Operating loss	(34,718)	(32,376)	(19,536)
Finance income / (costs) - net	(6,647)	15	60
Loss before tax	(41,365)	(32,361)	(19,476)
Income taxes	(1)	(4)	(1)
Loss for the period	(41,366)	(32,365)	(19,477)
Other comprehensive income / (loss)			
Items that will not be reclassified to profit or loss			
Equity investments at fair value OCI - net change in			
fair value	(242)	(632)	(4,731)
Other comprehensive income / (loss)	(242)	(632)	(4,731)
Total comprehensive Loss	(41,608)	(32,997)	(24,208)
Earnings / (loss) per share in € per share (undiluted = diluted)	(0.50)	(0.50)	(0.32)
Weighted number of common shares outstanding	83,471,559	64,242,396	60,514,407

# $\label{eq:Affined N.V.} Affimed N.V. \\ Consolidated statements of financial position (in \ \ \ \ \ \ thousand)$

	December 31, 2020	December 31, 2019
ASSETS		
Non-current assets		
Intangible assets	1,718	137
Leasehold improvements and equipment	2,226	2,291
Long term financial assets	20,042	3,193
Right-of-use assets	940	824
	24,926	6,445
Current assets		
Cash and cash equivalents	146,854	95,234
Financial assets	0	8,902
Trade and other receivables	2,439	1,482
Inventories	246	296
Other assets	1,260	0
	150,799	105,914
TOTAL ASSETS	175,725	112,359
EQUITY AND LIABILITIES		
Equity		
Issued capital	983	762
Capital reserves	345,164	270,451
Fair value reserves	1,720	1,962
Accumulated deficit	(275,874)	(234,508)
Total equity	71,993	38,667
Non-current liabilities		
Borrowings	231	278
Contract liabilities	35,992	37,961
Lease liabilities	482	272
Total non-current liabilities	36,705	38,511
Current liabilities		
Trade and other payables	11,394	10,674
Provisions	0	517
Borrowings	92	2,105
Lease liabilities	492	532
Contract liabilities	55,049	21,353
Total current liabilities	67,027	35,181
TOTAL EQUITY AND LIABILITIES	175,725	112,359

# $\label{eq:Affined N.V.} Affimed N.V. \\ Consolidated statements of cash flows (in \ \ \ \ \ \ thousand)$

	2020	2019	2018
Cash flow from operating activities			
Income / (loss) for the period	(41,366)	(32,365)	(19,477)
Adjustments for the period:			
- Income taxes	1	4	1
- Depreciation and amortisation	1,115	906	403
- Net gain / loss from disposal of leasehold improvements and equipment	34	(5)	25
- Share based payments	3,381	2,469	2,035
- Finance income / costs—net	6,647	(15)	(60)
	(30,188)	(29,006)	(17,073)
Change in trade and other receivables	(1,065)	33	(322)
Change in inventories	50	(36)	(19)
Change in other assets	(1,260)	340	121
Change in trade, other payables, provisions and contract liabilities	12,848	(791)	66,856
Cash used in operating activities	(19,615)	(29,460)	49,563
Interest received	294	628	218
Paid interest	(78)	(224)	(342)
Paid income tax	(1)	0	(1)
Net cash used in operating activities	(19,400)	(29,056)	49,438
Cash flow from investing activities			
Purchase of intangible assets	(9)	(150)	(30)
Purchase of leasehold improvements and equipment	(431)	(1,324)	(691)
Cash received from the sale of leasehold improvements and equipment	0	0	1
Cash paid for investments in financial assets	(8,101)	(45,131)	(14,029)
Cash received from maturity of financial assets	16,547	50,945	0
Cash paid for investments in long term financial assets	0	0	(861)
Net cash used for investing activities	8,006	4,340	(15,610)
Cash flow from financing activities			
Proceeds from issue of common shares	74,195	31,373	25,113
Transaction costs related to issue of common shares	(2,294)	(2,215)	(1,701)
Proceeds from borrowings	0	562	0
Repayment of lease liabilities	(521)	(405)	0
Repayment of borrowings	(2,128)	(3,277)	(2,917)
Cash flow from financing activities	69,252	26,038	20,495
Exchange-rate related changes of cash and cash equivalents	(6,238)	(917)	669
Net changes to cash and cash equivalents	57,858	1,322	54,323
Cash and cash equivalents at the beginning of the period	95,234	94,829	39,837
Cash and cash equivalents at the end of the period	146,854	95,234	94,829

# $\label{eq:Affined N.V.} Affimed N.V. \\ Consolidated statements of changes in equity (in § thousand)$

	Issued capital	Capital reserves	Fair value reserves	Accumulated deficit	Total equity
Balance as of January 1, 2018	468	213,778	7,325	(182,667)	38,904
Issue of common shares	156	23,171			23,327
Exercise of share based payment awards		71			71
Equity-settled share based payment awards		2,035			2,035
Loss for the period				(19,477)	(19,477)
Other comprehensive income			(4,731)		(4,731)
Balance as of December 31, 2018	624	239,055	2,594	(202,144)	40,129
Balance as of January 1, 2019	624	239,055	2,594	(202,144)	40,129
Issue of common shares	138	28,901			29,039
Exercise of share based payment awards		26			26
Equity-settled share based payment awards		2,469			2,469
Loss for the period				(32,365)	(32,365)
Other comprehensive income			(632)		(632)
Balance as of December 31, 2019	762	270,451	1,962	(234,508)	38,667
Balance as of January 1, 2020	762	270,451	1,962	(234,508)	38,667
Issue of common shares	205	68,341			68,546
Exercise of share based payment awards	16	2,991			3,007
Equity-settled share based payment awards		3,381			3,381
Loss for the period				(41,366)	(41,366)
Other comprehensive income			(242)		(242)
Balance as of December 31, 2020	983	345,164	1,720	(275,874)	71,993