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 March, 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): \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): \Box

INCORPORATION BY REFERENCE

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.

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: March 23, 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 March 23, 2023.



PRESS RELEASE

Affimed Reports 2022 Financial Results and Operational Progress

- AFM13 combination with AB-101 NK cells: On track for IND filing in H1 2023 and initiation of clinical study in 2023
- AFM13 monotherapy REDIRECT data: Oral presentation at the AACR annual meeting
- AFM24: Data from the three ongoing studies expected to be presented at scientific conferences in Q2 or Q3 of 2023
- AFM28: Clinical phase 1 study is open and recruiting; clinical trial applications now approved in four European countries including Belgium, France, Denmark and Spain
- Anticipated cash runway into 2025: As of December 31, 2022, cash and cash equivalents were €190.3 million

Heidelberg, Germany, March 23, 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 reported financial results for the year ended December 31, 2022, and provided an update on clinical and corporate progress.

"During 2022, we presented data across our pipeline that show our innate cell engagers can deliver unprecedented efficacy when combined with NK cells, can activate and direct cytotoxic T cells to tumor cells, and can deliver meaningful single agent activity with a differentiated safety profile," said Adi Hoess, Chief Executive Officer at Affimed. "Supported by a cash runway into 2025, our Company is well positioned to execute on our strategic imperatives, with multiple catalysts across our pipeline expected in 2023. We are excited about this next critical stage of development which we believe can unlock the tremendous value of our platform."

Program Updates

AFM13 (CD30/CD16A)

• In January 2023, Affimed received feedback from the Food and Drug Administration (FDA) to its pre-investigational new drug (IND) meeting request in support of a planned clinical study to investigate AFM13 in combination with Artiva's AB-101 natural killer (NK) cells. The Company is on track to submit the IND in the first half of 2023. Pending IND clearance, Affimed expects to initiate the combination clinical trial in 2023.

 AFM13-104: In December 2022, at the American Society of Hematology annual meeting, Affimed reported updated data from AFM13-104, the investigator sponsored trial (IST) led by The University of Texas MD Anderson Cancer Center investigating the combination of AFM13 combined with cord blood-derived NK cells followed by AFM13 monotherapy.

AFM13 in combination with NK cells showed very high overall and complete response rates in 41 heavily pre-treated CD30-positive Hodgkin lymphoma (HL) and Non-Hodgkin lymphoma (NHL) patients.

Patients in the study had a median of seven prior lines of treatment and all patients had failed to demonstrate objective response to immediate prior line of therapy.

In the 35 patients treated at the recommended phase 2 dose (RP2D), a 94% objective response rate (ORR) and a complete response (CR) rate of 71% were observed.

In 31 patients with Hodgkin lymphoma treated at the RP2D, an ORR of 97% and a CR rate of 77% were observed.

In four NHL patients treated at the RP2D, three objective responses, including one CR in a patient with peripheral T-cell lymphoma, were observed.

63% of patients treated at the RP2D with at least 6 months of follow-up after the initial infusion (n=24) remained in complete response for at least 6 months. In addition, the treatment was well tolerated with no cases of cytokine release syndrome, immune effector cell-associated neurotoxicity or graft versus host disease observed.

Affimed expects to present updated data from this combination study at a scientific conference later in 2023.

• AFM13-202: An abstract highlighting AFM13 data from the monotherapy study (REDIRECT) investigating efficacy in patients with CD30-positive relapsed/refractory peripheral T cell lymphomas (PTCL) has been accepted for an oral presentation at the 2023 American Association for Cancer Research (AACR) annual meeting.

AFM24 (EGFR/CD16A)

• Affimed expects to provide data updates from the three ongoing studies at scientific conferences in Q2 or Q3 of 2023. For AFM24-101, the Company expects to present data from approximately 15 patients from each of the non-small cell lung cancer and colorectal cancer cohorts. For AFM24-102 and AFM24-103, the update is expected to include data from the dose escalation portion of the respective clinical trials.

- 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: In 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, a 480 mg weekly dose of AFM24 was confirmed as the R2PD.

The expansion cohorts for AFM24-102, which include patients with non-small cell lung cancer (EGFR wildtype), gastric and gastroesophageal junction adenocarcinoma, and a basket cohort evaluating pancreatic/hepatocellular/biliary tract cancer, are now open and enrolling patients. The treatment showed a well-managed safety profile to date.

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 dose- limiting toxicities (DLTs) observed to date. The Company is recruiting three additional patients to confirm the 480 mg dose as the RP2D.

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)

In December 2022, the Company announced that Clinical Trial Applications (CTAs) were cleared in France and Spain. Since then, Belgium and Denmark have also approved the Company's CTAs. The phase 1 study is now open and recruiting patients.

AFM28 is Affimed's tetravalent, bispecific CD123- and CD16A-binding innate cell engager (ICE®) designed to bring a new immunotherapeutic approach to patients with CD123-positive myeloid malignancies, including Acute Myeloid Leukemia and Myelodysplastic Syndrome (MDS). It engages NK cells to initiate tumor cell killing via antibody-dependent cellular cytotoxicity (ADCC), even at low CD123 expression levels.

Clinical development of AFM28 is planned as both single-agent and in combination with NK cells in patients with CD123+ myeloid disease.

Partnerships and Collaborations

Partnered programs with Genentech and Affivant Sciences (a Roivant company) continue to progress.

During 2022, Affimed continued to work with Genentech pursuant to the previously disclosed research collaboration and license agreement between the companies and handed over a number of product candidates for further investigation by Genentech.

Affivant Sciences submitted two preclinical abstracts for AFVT-2101 (formerly AFM32) which have been accepted for poster presentation at the AACR annual meeting in April 2023. Affivant expects to submit an IND for AFVT-2101 in the first half of 2023.

Full Year 2022 Financial Highlights

Affimed's consolidated financial statements are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standard Board (IASB). The consolidated financial statements are presented in Euros (\mathfrak{C}) , the Company's functional and presentation currency.

As of December 31, 2022, cash and cash equivalents were €190.3 million, with an anticipated cash runway into 2025.

Net cash used in operating activities for the year ended December 31, 2022 was €104.9 million compared to €86.6 million in 2021.

Total revenue for the year ended December 31, 2022, was €41.4 million compared with €40.4 million for the year ended December 31, 2021. Revenue predominately relates to the Genentech and Roivant collaborations.

Research and development expenses for 2022 increased by 21.3% from €81.5 million in 2021 to €98.8 million in 2022. The increase was primarily due to higher expenses associated with the development of the AFM24 and AFM28 programs, a result of an increase in manufacturing of clinical trial material and costs for the preparation of the filing of the IND application, an increase in costs associated with other early-stage programs and infrastructure, and an increase in share-based payment expenses.

General and administrative expenses increased 32.4% from €24.2 million in 2021, to €32.1 million in 2022. The increase predominately relates to higher personnel and share-based payment expenses and an increase in insurance premiums and higher consulting costs.

Net finance income for the year decreased from €6.5 million in 2021, to €2.1 million in 2022. Net finance income is largely due to foreign exchange gains related to assets denominated in U.S. dollars as a result of currency fluctuations between the U.S. dollar and Euro during the year.

Net loss for the year ended December 31, 2022, was €86.0 million, or €0.60 loss per common share compared with a net loss of €57.5 million, or €0.48 loss per common share, for the year ended December 31, 2021.

The weighted number of common shares outstanding for the year ended December 31, 2022 was 142.4 million.

Additional information regarding these results will be included in the notes to the consolidated financial statements as of December 31, 2022, included in Affimed's filings 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 IASB. 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 on March 23, 2023, at 8:30 a.m. EDT / 13:30 CET to discuss full year and Q4 2022 financial results and corporate developments.

The conference call will be available via phone and webcast. The live audio webcast of the call will be available in the "Webcasts" section on the "Investors" page of the Affimed website at https://www.affimed.com/investors/webcasts-and-corporate-presentation/. To access the call by phone, please use link:

https://register.vevent.com/register/BIbfecf0c35a2946dc88d3ae439cb5d3e2, and you will be provided with dial-in details and a pin number.

Note: To avoid delays, we encourage participants to dial into the conference call 15 minutes ahead of the scheduled start time. 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: www.affimed.com.

Forward-Looking Statement

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 macroeconomic trends that may affect the industry or the Company, such as the instability in the banking sector experienced in the first quarter of 2023, 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.

Investor Relations Contact

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Affimed N.V. Consolidated statements of comprehensive loss (in € thousand)

	2022	2021	2020
Revenue	41,353	40,366	28,360
Other income – net	1,417	1,310	626
Research and development expenses	(98,814)	(81,488)	(49,989)
General and administrative expenses	(32,075)	(24,218)	(13,715)
Operating loss	(88,119)	(64,030)	(34,718)
Finance income / (costs) – net	2,117	6,509	(6,647)
Loss before tax	(86,002)	(57,521)	(41,365)
Income taxes	(2)	(2)	(1)
Loss for the period	(86,004)	(57,523)	(41,366)
Other comprehensive loss			
Items that will not be reclassified to profit or loss			
Equity investments at fair value OCI – net change in fair value	(6,047)	(7,693)	(242)
Other comprehensive loss	(6,047)	(7,693)	(242)
Total comprehensive loss	(92,051)	(65,216)	(41,608)
Basic and diluted loss per share in € per share (undiluted = diluted)	(0.60)	(0.48)	(0.50)
Weighted number of common shares outstanding	142,362,294	119,502,384	83,471,559

Affimed N.V. Consolidated statements of financial position (in € thousand)

	December 31, 2022	December 31, 2021
ASSETS		
Non-current assets		
Intangible assets	58	1,607
Leasehold improvements and equipment	3,823	3,814
Long-term financial assets	0	12,348
Right-of-use assets	561	972
	4,442	18,741
Current assets		
Cash and cash equivalents	190,286	197,630
Trade and other receivables	2,697	4,809
Inventories	628	421
Other assets and prepaid expenses	2,459	3,534
	196,070	206,394
TOTAL ASSETS	200,512	225,135
EQUITY AND LIABILITIES		
Equity		
Issued capital	1,493	1,234
Capital reserves	582,843	474,087
Fair value reserves	(1,231)	(5,973)
Accumulated deficit	(430,190)	(333,397)
Total equity	152,915	135,951
Non current liabilities		
Borrowings	11,687	17,060
Contract liabilities	1,083	7,209
Lease liabilities	176	368
Total non-current liabilities	12,946	24,637
Current liabilities		
Trade and other payables	19,077	18,860
Borrowings	5,930	580
Lease liabilities	396	683
Contract liabilities	9,248	44,424
Total current liabilities	34,651	64,547
TOTAL EQUITY AND LIABILITIES	200,512	225,135

Affimed N.V. Consolidated statements of cash flows (in € thousand)

	2022	2021	2020
Cash flow from operating activities			
Loss for the period	(86,004)	(57,523)	(41,366)
Adjustments for the period:			
- Income taxes	2	2	1
- Depreciation and amortization	2,899	1,334	1,115
- Net gain from disposal of leasehold improvements and equipment	0	0	34
- Share-based payments	19,110	11,820	3,381
- Finance income / (costs) – net	(2,117)	(6,509)	6,647
	(66,110)	(50,876)	(30,188)
Change in trade and other receivables	2,113	(2,369)	(1,065)
Change in inventories	(207)	(175)	50
Change in other assets and prepaid expenses	1,075	(2,274)	(1,260)
Change in trade, other payables, provisions and contract liabilities	(41,048)	(29,990)	12,848
	(104,177)	(85,684)	(19,615)
Interest received	564	0	294
Paid interest	(1,277)	(905)	(78)
Paid income tax	(2)	(2)	(1)
Net cash used in operating activities	(104,892)	(86,591)	(19,400)
Cash flow from investing activities			
Purchase of intangible assets	(37)	(1,654)	(9)
Purchase of leasehold improvements and equipment	(659)	(2,196)	(431)
Cash reeceived from the sale of financial assets	6,301	0	0
Cash paid for investments in financial assets	0	0	(8,101)
Cash received from maturity of financial assets	0	0	16,547
Net cash generated / (used) for investing activities	5,605	(3,850)	8,006
Cash flow from financing activities			·
Proceeds from issue of common shares, including exercise of share-based payment awards	95,907	124,460	74,195
Transaction costs related to issue of common shares	(6,037)	(7,412)	(2,294)
Proceeds from borrowings	0	17,500	0
Transaction costs related to borrowings	0	(311)	0
Repayment of lease liabilities	(733)	(564)	(521)
Repayment of borrowings	(580)	(92)	(2,128)
Cash flow from financing activities	88,557	133,581	69,252
Exchangerate related changes of cash and cash equivalents	3,386	7,636	(6,238)
Net changes to cash and cash equivalents	(10,730)	43,140	57,858
Cash and cash equivalents at the beginning of the period	197,630	146,854	95,234
Cash and cash equivalents at the end of the period	190,286	197,630	146,854
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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, 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 loss			(242)		(242)
Balance as of December 31, 2020	983	345,164	1,720	(275,874)	71,993
Balance as of January 1, 2021	983	345,164	1,720	(275,874)	71,993
Issue of common shares	240	114,197			114,437
Exercise of share-based payment awards	11	2,906			2,917
Equity-settled share-based payment awards		11,820			11,820
Loss for the period				(57,523)	(57,523)
Other comprehensive loss			(7,693)		(7,693)
Balance as of December 31, 2021	1,234	474,087	(5,973)	(333,397)	135,951
Balance as of January 1, 2022	1,234	474,087	(5,973)	(333,397)	135,951
Issue of common shares	259	89,545			89,804
Exercise of share-based payment awards	0	101			101
Equity-settled share-based payment awards		19,110			19,110
Transfer of cumulative loss on sale of financial assets			10,789	(10,789)	0
Loss for the period				(86,004)	(86,004)
Other comprehensive loss			(6,047)		(6,047)
Balance as of December 31, 2022	1,493	582,843	(1,231)	(430,190)	152,915