



## PRESS RELEASE

### Affimed Reports Second Quarter 2022 Financial Results and Highlights Recent Operational Progress

- AFM13 monotherapy: On track to report topline data of the registration-directed REDIRECT trial in the fourth quarter of 2022
- AFM13 combination with natural killer (NK) cells: On track to report updated data at a scientific conference in the fourth quarter of 2022
- AFM24: Studies continue to enroll; data updates expected at scientific conferences in the second half of 2022
- AFM28: Following interactions with FDA, strategic decision to focus early clinical development in non-U.S. jurisdictions; clinical study now expected to start in the first half of 2023
- Cash and cash equivalents as of June 30, 2022 were approximately €237.2 million with anticipated cash runway into mid-2024
- Conference call and webcast scheduled for August 11, 2022 at 8:30 a.m. EDT/14:30 CEST

**Heidelberg, Germany, August 11, 2022** – 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 second quarter ended June 30, 2022 and provided updates on preclinical, clinical and corporate progress.

“During the second quarter, we completed a public offering that enables Affimed to invest in its lead programs through key inflection points,” said Dr. Adi Hoess, CEO of Affimed. “The second half of 2022 is shaping up to be very exciting with data updates from AFM13 monotherapy and combination studies and our AFM24 program at scientific conferences.”

## **Clinical Stage Program Updates**

### **AFM13 (CD30/CD16A)**

- The Company completed enrollment of its REDIRECT study (AFM13-202). REDIRECT is a phase 2, registration-directed study of AFM13 monotherapy in patients with relapsed/refractory CD30-positive peripheral T-cell lymphoma (PTCL).

Top-line data are expected to be reported in the fourth quarter of 2022. The focus of the initial data release will be on the overall response rate assessed by a blinded independent review committee and the preliminary assessment of response duration.

- Enrollment continues in the phase 1/2 study in collaboration with The University of Texas MD Anderson Cancer Center (MD Anderson) evaluating cord-blood derived NK cells pre-complexed with AFM13 followed by single agent AFM13 in patients with relapsed/refractory CD30+ lymphomas.

Data presented at the 2022 Annual Meeting of the American Association for Cancer Research (AACR 2022) in the Clinical Trials Plenary Session by Dr. Yago Nieto, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson, reported that after a second cycle of treatment at the recommended phase 2 dose (RP2D), the complete response rate increased from 38% (5/13) as reported in December 2021 to 62% (8/13).

The overall objective response rate (ORR) remained at 100% and the treatment was safe and well tolerated by patients, enabling MD Anderson to continue treatment with up to four cycles as per the approved amended protocol. The main treatment-related side effect being infusion-related reactions. Investigators did not observe any cases of cytokine release syndrome (CRS), neurotoxicity or graft versus host disease often associated with T-cell therapies. In general, side effects observed in the trial were transient and did not lead to treatment delays or discontinuation.

Durability of response data presented at AACR 2022 for patients treated at the RP2D was also promising. Of the eight patients who achieved a complete response (CR), seven remained in CR at median follow-up of 6.5 months, including two patients who remained in response after 10 months and two who received a consolidation autologous stem cell transplant (SCT).

The approved amendment to the AFM13-104 trial protocol allows for an increase in the number of CD30-positive lymphoma patients treated at the RP2D to 40 – including Hodgkin and non-Hodgkin’s lymphoma patients. Furthermore, under the amended protocol, patients can receive up to four cycles of treatment.

Enrollment continues to progress and as of July 31, 2022 30 patients have now been treated, including 24 at the RP2D. 11 additional patients have been treated at the RP2D since the AACR 2022 data cutoff date.

The Company and MD Anderson expect to report updates on the study at a scientific conference in the fourth quarter of 2022.

The Company continues to make progress with third parties to ensure access to an off-the-shelf, cryopreserved NK cell product and expects to announce the development path for AFM13 with a specific NK cell in the second half of 2022.

Affimed is preparing for a meeting with the FDA later this year to discuss next development steps for this program and expects to provide an update once it receives feedback.

#### **AFM24 (EGFR/CD16A)**

- The Company is continuing enrollment in the expansion phase of the monotherapy study at the RP2D (480 mg). The expansion cohorts include patients with renal cell carcinoma (clear cell), non-small cell lung cancer (EGFR mutant), and colorectal cancer (KRAS wild-type, MSS).
- Enrollment also continues in two combination studies: a phase 1/2a combination study of AFM24 with the anti-PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) (AFM24-102) and a phase 1/2a combination of AFM24 with SNK01, NKGen Biotech’s ex vivo expanded and activated autologous NK cell therapy (AFM24-103).

AFM24-102 is now enrolling patients at the 480 mg dose level of AFM24. The first cohort (160 mg) was completed successfully with no reports of dose limiting toxicities. AFM24-102 includes the treatment of patients with non-small cell lung cancer (EGFR wild-type), gastric and gastroesophageal junction adenocarcinoma and pancreatic/hepatocellular/biliary tract cancer. AFM24-103 is focused on the treatment of patients with non-small cell lung cancer (NSCLC, EGFR wild-type),

squamous cell carcinoma of the head and neck, and colorectal cancer (KRAS wild-type/mutant, MSS).

Updates from the monotherapy study, including clinical data from the dose escalation phase will be shown at ESMO 2022. An additional update including correlative science data is expected to be presented at a scientific conference later this year. Affimed also expects to provide updates from the combination studies in the second half of 2022, including data from the dose escalation phase of AFM24-102 at a scientific conference in the fourth quarter of 2022.

### **Preclinical Programs**

#### **AFM28 (CD123/CD16A)**

- As planned, the Company submitted an investigational new drug (IND) application to the FDA in June. Following feedback from the FDA related to the design of the dose escalation study, Affimed has made a strategic decision to voluntarily withdraw the IND. The Company plans to focus early clinical development of AFM28 in jurisdictions outside of the U.S.
- The Company now anticipates initiating the phase 1 clinical study in the first half of 2023.

AFM28 is Affimed's wholly-owned, bispecific, tetravalent innate cell engager (ICE<sup>®</sup>) that targets CD16A on NK cells and macrophages, and CD123 on leukemic blasts and leukemic stem cells that are prevalent in acute myeloid leukemia (AML).

### **Preclinical Pipeline**

Affimed is continuing to innovate and generate several novel ICE<sup>®</sup> molecules derived from its proprietary ROCK<sup>®</sup> platform.

### **Partnerships and Collaborations**

Partnered programs with both Genentech and Roivant continue to progress according to plan. Affimed is eligible for additional proceeds from meeting pre-clinical and early regulatory achievement milestones.

### **Scientific Advisory Board**

During the quarter, the Company established an independent advisory panel made up of distinguished opinion leaders with scientific and clinical expertise in innate immunity and oncology. The Scientific Advisory Board (SAB) will provide guidance on the development

strategy across preclinical and clinical development candidates as well as opportunities to apply our platform to cancer indications of high unmet need. All SAB members are leaders in a broad range of areas relevant to Affimed's approach to developing cancer therapies including immuno-oncology, the biology of NK cells, lymphomas, leukemias, and solid tumors.

## **Second Quarter 2022 Financial Highlights**

Affimed's consolidated financial statements are prepared in accordance with IFRS as issued by the International Accounting Standard Board (IASB). The consolidated financial statements are presented in euros, the Company's functional and presentation currency. As of June 30, 2022 cash and cash equivalents totaled €237.2 million compared to €197.6 million on December 31, 2021.

Based on the Company's current operating plan and assumptions, cash and cash equivalents are expected to support operations into mid-2024.

Net cash used in operating activities for the quarter ended June 30, 2022 was €26.5 million compared to €17.3 million for the quarter ended June 30, 2021.

Total revenue for the quarter ended June 30, 2022 was €7.3 million compared with €9.7 million for the quarter ended June 30, 2021. Revenue predominately relates to the Genentech and Roivant collaborations.

Research and development expenses decreased by 4% from €21.8 million in the quarter ended June 30, 2021 to €20.8 million for the quarter ended June 30, 2022. The decrease was primarily due to lower expenses associated with the development of the AFM13 and AFM24 programs, a result of a decrease in procurement of clinical trial material.

General and administrative expenses increased 54% from €5.4 million in the quarter ended June 30, 2021 to €8.4 million in the quarter ended June 30, 2022. The increase predominately relates to higher personnel, higher share-based payment expenses and increased insurance premiums.

Net finance income/(costs) increased from costs of €1.6 million for the quarter ended June 30, 2021 to income of €2.3 million for the quarter ended June 30, 2022. Net finance income/(cost) is largely made up of foreign exchange gains and losses related to assets denominated in U.S. dollars as a result of currency fluctuations between the U.S. dollar and the Euro during the year.

Net loss for the quarter ended June 30, 2022 was €19.4 million, or €0.13 loss per common share compared with a net loss of €18.8 million, or €0.16 loss per common share for the quarter ended June 30, 2021.

The weighted number of common shares outstanding for the quarter ended June 30, 2022 was 147.3 million.

Additional information regarding these results is included in the notes to the consolidated financial statements as of June 30, 2022 which will be 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 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 on August 11, 2022 at 8:30 a.m. EDT / 14:30 CEST to discuss second quarter 2022 financial results and corporate developments. The conference call will be available via phone and webcast.

To access the call, please dial +1 (866) 374-5140 for U.S. callers, or +1 (404) 400-0571 for international callers, and use PIN: 54780189# 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

<https://www.affimed.com/investors/webcasts-and-corporate-presentation/>.

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](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, the impact on our business by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties, such as the Russia-Ukraine conflict 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**

Alexander Fudukidis

Director, Investor Relations

E-Mail: [a.fudukidis@affimed.com](mailto:a.fudukidis@affimed.com)

Tel.: +1 (917) 436-8102

**AFFIMED N.V.**

**CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

Unaudited consolidated interim statements of comprehensive income / (loss)

(in € thousand)

	For the three months ended June 30		For the six months ended June 30	
	2022	2021	2022	2021
<b>Revenue</b>	<b>7,301</b>	<b>9,707</b>	<b>15,307</b>	<b>21,366</b>
Other income – net	240	332	524	479
Research and development expenses	(20,829)	(21,800)	(39,208)	(33,205)
General and administrative expenses	(8,374)	(5,439)	(15,419)	(9,925)
<b>Operating loss</b>	<b>(21,662)</b>	<b>(17,200)</b>	<b>(38,796)</b>	<b>(21,285)</b>
<b>Finance income / (costs) – net</b>	<b>2,253</b>	<b>(1,552)</b>	<b>2,724</b>	<b>3,947</b>
<b>Loss before tax</b>	<b>(19,409)</b>	<b>(18,752)</b>	<b>(36,072)</b>	<b>(17,338)</b>
Income taxes	0	0	(2)	(2)
<b>Loss for the period</b>	<b>(19,409)</b>	<b>(18,752)</b>	<b>(36,074)</b>	<b>(17,340)</b>
<b>Other comprehensive income / (loss)</b>				
<b>Items that will not be reclassified to profit or loss</b>				
Equity investments at fair value OCI – net change in fair value	(599)	(4,097)	(6,773)	(5,349)
<b>Other comprehensive income / (loss)</b>	<b>(599)</b>	<b>(4,097)</b>	<b>(6,773)</b>	<b>(5,349)</b>
<b>Total comprehensive income / (loss)</b>	<b>(20,008)</b>	<b>(22,849)</b>	<b>(42,847)</b>	<b>(22,689)</b>
<b>Basic and diluted earnings / (loss) per share in € per share (undiluted = diluted)</b>	<b>(0.13)</b>	<b>(0.16)</b>	<b>(0.27)</b>	<b>(0.15)</b>
<b>Weighted number of common shares outstanding</b>	<b>147,326,291</b>	<b>119,645,207</b>	<b>135,385,254</b>	<b>117,924,831</b>



**Consolidated interim statements of financial position**  
**(in € thousand)**

	<b>June 30, 2022</b> <b>(unaudited)</b>	<b>December 31, 2021</b>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	1,553	1,607
Leasehold improvements and equipment	3,684	3,814
Long-term financial assets	0	12,348
Right-of-use assets	877	972
	<hr/> 6,114	<hr/> 18,741
<b>Current assets</b>		
Cash and cash equivalents	237,232	197,630
Trade and other receivables	5,524	4,809
Inventories	571	421
Assets held for sale	4,057	0
Other assets and prepaid expenses	7,407	3,534
	<hr/> 254,791	<hr/> 206,394
<b>TOTAL ASSETS</b>	<b>260,905</b>	<b>225,135</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Issued capital	1,493	1,234
Capital reserves	573,544	474,087
Fair value reserves	(9,927)	(5,973)
Accumulated deficit	(372,290)	(333,397)
<b>Total equity</b>	<hr/> <b>192,820</b>	<hr/> <b>135,951</b>
<b>Non current liabilities</b>		
Borrowings	14,368	17,060
Contract liabilities	1,392	7,209
Lease liabilities	317	368
<b>Total non-current liabilities</b>	<hr/> <b>16,077</b>	<hr/> <b>24,637</b>
<b>Current liabilities</b>		
Trade and other payables	12,760	18,860
Borrowings	3,498	580
Lease liabilities	613	683
Contract liabilities	35,137	44,424
<b>Total current liabilities</b>	<hr/> <b>52,008</b>	<hr/> <b>64,547</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>260,905</b>	<b>225,135</b>

**Unaudited consolidated interim statements of cash flows**  
**(in € thousand)**

**For the six months ended June 30**

	<b>2022</b>	<b>2021</b>
<b>Cash flow from operating activities</b>		
Income / (loss) for the period	(36,074)	(17,340)
Adjustments for the period:		
- Income taxes	2	2
- Depreciation and amortization	703	624
- Share-based payments	9,872	4,695
- Finance income / costs – net	(2,724)	(3,947)
	<u>(28,221)</u>	<u>(15,966)</u>
Change in trade and other receivables	(715)	(1,324)
Change in inventories	(150)	(366)
Change in other assets and prepaid expenses	(3,873)	924
Change in trade, other payables, provisions and contract liabilities	(21,372)	(16,262)
	<u>(54,331)</u>	<u>(32,994)</u>
Interest received	82	0
Paid interest	(653)	(377)
Paid income tax	(2)	(2)
<b>Net cash used in operating activities</b>	<u><b>(54,904)</b></u>	<u><b>(33,373)</b></u>
<b>Cash flow from investing activities</b>		
Purchase of intangible assets	0	(5)
Purchase of leasehold improvements and equipment	(194)	(1,502)
Cash received from the sale of financial assets	1,518	0
<b>Net cash used for investing activities</b>	<u><b>1,324</b></u>	<u><b>(1,507)</b></u>
<b>Cash flow from financing activities</b>		
Proceeds from issue of common shares, including exercise of share-based payment awards	95,907	103,242
Transaction costs related to issue of common shares	(5,894)	(6,447)
Proceeds from borrowings	0	10,000
Transaction costs related to borrowings	0	(236)
Repayment of lease liabilities	(352)	(228)
Repayment of borrowings	(47)	(46)
<b>Cash flow from financing activities</b>	<u><b>89,614</b></u>	<u><b>106,285</b></u>
<b>Exchange-rate related changes of cash and cash equivalents</b>	<b>3,568</b>	<b>4,417</b>
<b>Net changes to cash and cash equivalents</b>	<b>36,034</b>	<b>71,405</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<u><b>197,630</b></u>	<u><b>146,854</b></u>
<b>Cash and cash equivalents at the end of the period</b>	<u><b>237,232</b></u>	<u><b>222,676</b></u>

**Unaudited consolidated interim statements of changes in equity  
(in € thousand)**

	Issued capital	Capital reserves	Fair Value reserves	Accumulated deficit	Total equity
<b>Balance as of January 1, 2021</b>	<b>983</b>	<b>345,164</b>	<b>1,720</b>	<b>(275,874)</b>	<b>71,993</b>
Issue of common shares	205	94,135			94,340
Exercise of share-based payment awards	9	2,531			2,540
Equity-settled share-based payment awards		4,695			4,695
Loss for the period				(17,340)	(17,340)
Other comprehensive loss			(5,349)		(5,349)
<b>Balance as of June 30, 2021</b>	<b>1,197</b>	<b>446,525</b>	<b>(3,629)</b>	<b>(293,214)</b>	<b>150,879</b>
<b>Balance as of January 1, 2022</b>	<b>1,234</b>	<b>474,087</b>	<b>(5,973)</b>	<b>(333,397)</b>	<b>135,951</b>
Issue of common shares	259	89,484			89,743
Exercise of share-based payment awards		101			101
Equity-settled share-based payment awards		9,872			9,872
Transfer of cumulative loss on sale of financial assets			2,819	(2,819)	0
Loss for the period				(36,074)	(36,074)
Other comprehensive loss			(6,773)		(6,773)
<b>Balance as of June 30, 2022</b>	<b>1,493</b>	<b>573,544</b>	<b>(9,927)</b>	<b>(372,290)</b>	<b>192,820</b>