



**FOR IMMEDIATE RELEASE**

## **Affimed Reports Second Quarter 2019 Financial and Operational Results**

*Heidelberg, Germany, August 7, 2019* - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company committed to giving patients back their innate ability to fight cancer, today reported financial and operating results for the second quarter ended June 30, 2019.

“After reaching agreement with the U.S. Food and Drug Administration on the study protocol design, we are now in the process of preparing to initiate the AFM13 registration-directed Phase 2 study,” said Dr. Adi Hoess, Affimed’s CEO. “The recent positive final and interim results from two clinical studies of AFM13 add to the growing body of evidence supporting AFM13’s activity in CD30-positive lymphoma patients, and give us increased confidence in the potential of AFM13 to demonstrate clinical benefit in CD30-positive peripheral T cell lymphoma. To execute the Phase 2 study and to further advance our internal and partnered CD16A-targeting innate cell engager pipeline, we have significantly strengthened our organization through the addition of multiple key hires in the U.S. and Germany of individuals who have substantial drug development experience.”

### **Corporate Updates**

- Affimed strengthened its drug development team with the addition of experienced personnel in several key areas, including Regulatory Affairs, Clinical Development and Operations, Drug Safety, Chemistry, Manufacturing and Control (CMC), Drug Safety & Pharmacovigilance, Biostatistics and Commercial Strategy. The new hires previously held positions at Novartis, Pfizer Inc., Abbott, Eli Lilly and Company and other large pharmaceutical or biotechnology companies.
- In April, Affimed received a payment from Genentech triggered by the achievement of a preclinical milestone under its research collaboration to develop and commercialize novel natural killer (NK) cell engager-based immunotherapeutics based on Affimed’s ROCK® platform to treat multiple cancers.

- Affimed was added to the Russell 2000®, Russell 3000®, and Russell Microcap® Indexes, effective after the U.S. markets closed on Friday, June 28, 2019 as part of Russell's annual index rebalance process. Russell U.S. Indexes are widely used by investment managers and institutional investors as the basis for index funds and as benchmarks for active investment strategies.
- In June 2019, Affimed's subsidiary AbCheck entered into a five-year licensing agreement with Icosagen granting AbCheck access to Icosagen's QMCF protein production technology. Under the terms of the agreement, AbCheck acquires the rights to utilize Icosagen's QMCF technology platform for its commercial activities in antibody discovery.

## **Pipeline Updates**

### CD16A innate cell engager programs

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

- Affimed reached agreement with the U.S. Food and Drug Administration regarding the design of its planned Phase 2 registration-directed study of AFM13 as monotherapy in relapsed or refractory patients with CD30-positive peripheral T cell lymphoma (PTCL). The results, if positive, could form the basis for a Biologics License Application (BLA) submission and support an accelerated approval given the unmet medical need for safe and effective new treatments in this hard-to-treat patient population. The study will also enroll a cohort of patients with transformed mycosis fungoides, an aggressive subtype of cutaneous T cell lymphoma. Study start-up activities are under way, with study commencement anticipated in the second half of 2019.
- Updated data from an investigator-sponsored translational Phase 1b/2a study of AFM13 in patients with relapsed or refractory CD30-positive lymphoma with cutaneous manifestation led by Columbia University was presented at the International Conference on Malignant Lymphomas (ICML) in Lugano in June 2019. The data confirmed single-agent activity of AFM13 in CD30-positive lymphoma patients, with an objective response rate (ORR) of 50% (5 out of 10 patients). Tumor biopsies showed increased infiltration of NK cells in responders compared to non-responders, and evidence of NK cell-mediated killing.
- Affimed reported the final results from the Phase 1b dose escalation study of AFM13 plus pembrolizumab that showed encouraging efficacy in the intent-to-treat (ITT) patient population (n=30) with an ORR of 83%, including complete responses (CR) in 40% and partial responses (PR) in 43% of patients with hard-to-treat Hodgkin lymphoma. At the highest treated dose (n=24), patients showed an ORR of 88% (CR of 46% and PR of 42%) as determined by independent assessment. Overall, the combination of AFM13 and

pembrolizumab showed a favorable safety profile in patients, including some patients who did not respond to first-line chemotherapy and a subgroup of patients who were primary refractory to brentuximab vedotin. Importantly, a deepening of responses was reported over time in multiple patients. In addition, patients previously transplant-ineligible transitioned to transplant after achieving an objective response with the combination of AFM13 and pembrolizumab, thus increasing the chance for a cure. These positive results, taken together with data demonstrating single-agent activity of AFM13 in CD30-positive T cell lymphoma patients, form the basis for Affimed to initiate a registration-directed study of AFM13 as monotherapy in patients with PTCL.

- The combination of AFM13 with allogeneic NK cells represents a novel approach in order to further improve response rates and durability of responses in patients with relapsed/refractory CD30-positive lymphoma. In a preclinical collaboration with the University of Texas MD Anderson Cancer Center (MDACC), AFM13 has been shown to bind to CD16A with much higher affinity than other CD16A binding moieties such as monoclonal antibodies, thus enabling the formation of a stable complex of AFM13 pre-mixed with cord blood-derived allogeneic NK cells. This stable complex showed strong efficacy in *in vitro* and *in vivo* experiments, forming the basis for an investigator-sponsored Phase 1 study by MDACC. In the study, MDACC intends to administer this stable complex in different doses (numbers of pre-loaded NK cells) into patients with relapsed/refractory CD30-positive malignancies.

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

- AFM24 is a tetravalent, bispecific EGFR- and CD16A-binding innate cell engager from Affimed's ROCK® platform. It is designed to target EGFR-expressing solid tumors by a new mechanism of action that activates innate immunity. This is a differentiated approach from cetuximab and other EGFR targeting approaches that inhibit tumor growth by EGFR-mediated signal transduction. Affimed presented data at the American Association for Cancer Research (AACR) 2019 Annual Meeting that demonstrated AFM24's ability to bridge NK cells and macrophages to EGFR expressing tumor cell lines and induce lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), respectively. Due to AFM24's different mode of action these effects were independent of RAS mutational status. Importantly, AFM24 enhanced tumor infiltration of NK cells and elicited dose-dependent anti-tumor efficacy in *in vivo* tumor models. AFM24 showed reduced inhibition of EGFR phosphorylation relative to the monoclonal antibody cetuximab. Treatment of cynomolgus monkeys with AFM24 resulted in a favorable safety profile, even when treated at high dose levels, demonstrating AFM24's potential to have significantly lower toxicities in humans compared to standard

of care. Affimed currently anticipates submitting the investigational new drug (IND) application for AFM24 around the end of the third quarter 2019.

### **Technology Updates**

- Data describing Affimed's ROCK® antibody platform was published in the *mAbs* journal, titled, "Redirected optimized cell killing (ROCK®): A highly versatile multispecific fit-for-purpose antibody platform for engaging innate immunity." The paper discusses aspects of the modular platform, including the advantages of innate immune cell engagement over monoclonal antibodies and other engager concepts. The article also describes the potential of the ROCK® platform to engineer a fit-for-purpose innate immune cell engager format that can be equipped with unique CD16A domains, modules that influence pharmacokinetic properties and molecular architectures that influence the activation of immune effectors, as well as tumor targeting. The article is available at: <https://doi.org/10.1080/19420862.2019.1616506>.

### **Financial Highlights**

(Figures for the second quarter and six months ended June 30, 2019 and 2018 are unaudited.)

Cash, cash equivalents and current financial assets totaled €87.7 million as of June 30, 2019, compared to €108.8 million as of December 31, 2018. Based on its current operating and budget assumptions, Affimed anticipates that its cash, cash equivalents and current financial assets as of June 30, 2019 will enable the Company to fund its planned clinical development and early development activities into 2021.

Net cash used in operating activities was €18.9 million for the six months ended June 30, 2019, compared to net cash used in operating activities of €15.2 million for the six months ended June 30, 2018. The increase is primarily due to higher cash expenditure for research and development efforts.

Total revenue was €4.0 million for the three months ended June 30, 2019 compared to €0.2 million for the three months ended June 30, 2018. The increase in revenue is attributable to the recognition of €3.7 million as revenue from the Genentech collaboration in the second quarter of 2019.

Research and development (R&D) expenses for the second quarter of 2019 were €11.5 million, including accrued termination costs of €1.4 million associated with the wind-down activities for the two Phase 1 studies of AFM11. R&D expenses for the second quarter of 2018 were €7.1 million. The increase was primarily related to higher expenses related to manufacturing activities for clinical study material for AFM13, startup activities for the AFM13 registration study in PTCL,

early stage development and discovery activities, and the termination costs for the two AFM11 clinical studies.

General and administrative (G&A) expenses for the second quarter of 2019 were nearly unchanged at €2.3 million compared to €2.2 million for the second quarter of 2018.

Net loss was €10.3 million, or €0.17 per common share, for the second quarter of 2019, compared to a net loss of €8.0 million, or €0.13 per common share, for the second quarter of 2018.

### **Note on IFRS Reporting Standards**

Affimed prepares and reports the consolidated financial statements and financial information in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). None of the financial statements were prepared in accordance with Generally Accepted Accounting Principles (GAAP) 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, Wednesday, August 7, 2019 at 8:30 a.m. Eastern time to discuss the company's financial results and recent corporate developments. To access the call, please dial +1 (917) 720-0178 for U.S. callers, or +44 (0) 203 0095710 for international callers, and reference conference ID 9396039 approximately 15 minutes prior to the call. An audio webcast of the conference call can be accessed in the "Webcasts" section on the "Investors" page of the Affimed website at <https://www.affimed.com/investors/webcasts/>. A replay of the webcast will be available on Affimed's website shortly after the conclusion of the call and will be archived for 30 days following the call.

### **About Affimed N.V.**

Affimed (Nasdaq: AFMD) is a clinical stage biopharmaceutical company committed to giving patients back their innate ability to fight cancer. Affimed's fit-for-purpose ROCK® platform allows innate cell engagers to be designed for specific patient populations. The Company is developing single and combination therapies to treat hematologic and solid tumors. For more information, 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 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, 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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**Affimed N.V.**  
**Unaudited consolidated statements of comprehensive income/(loss) (in € thousand)**

	For the three months ended June 30		For the six months ended June 30	
	2019	2018	2019	2018
<b>Revenue</b>	<b>4,008</b>	<b>150</b>	<b>15,361</b>	<b>682</b>
Other income – net	197	49	283	38
Research and development expenses	(11,545)	(7,149)	(19,532)	(13,545)
General and administrative expenses	(2,342)	(2,164)	(4,776)	(4,202)
<b>Operating income / (loss)</b>	<b>(9,682)</b>	<b>(9,114)</b>	<b>(8,664)</b>	<b>(17,027)</b>
<b>Finance income / (costs) – net</b>	<b>(654)</b>	<b>1,100</b>	<b>180</b>	<b>811</b>
<b>Income / (loss) before tax</b>	<b>(10,336)</b>	<b>(8,014)</b>	<b>(8,484)</b>	<b>(16,216)</b>
Income taxes	(4)	0	(4)	(1)
<b>Income / (loss) for the period</b>	<b>(10,340)</b>	<b>(8,014)</b>	<b>(8,488)</b>	<b>(16,217)</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	(49)	406	24	211
<b>Other comprehensive income / (loss)</b>	<b>(49)</b>	<b>406</b>	<b>24</b>	<b>211</b>
<b>Total comprehensive income / (loss)</b>	<b>(10,389)</b>	<b>(7,608)</b>	<b>(8,464)</b>	<b>(16,006)</b>
<b>Earnings / (loss) per share in € per share (undiluted = diluted)</b>	<b>(0.17)</b>	<b>(0.13)</b>	<b>(0.14)</b>	<b>(0.28)</b>
<b>Weighted number of common shares outstanding</b>	<b>62,439,363</b>	<b>62,390,068</b>	<b>62,434,734</b>	<b>58,614,053</b>

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

	<b>June 30, 2019</b>	<b>December 31, 2018</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	168	56
Leasehold improvements and equipment	1,960	1,414
Long term financial assets	3,849	3,825
Right-of-use assets	653	0
	6,630	5,295
<b>Current assets</b>		
Cash and cash equivalents	63,987	94,829
Financial assets	23,726	13,974
Trade and other receivables	1,471	1,429
Inventories	330	260
Other assets	2,973	387
	92,487	110,879
<b>TOTAL ASSETS</b>	<b>99,117</b>	<b>116,174</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Issued capital	624	624
Capital reserves	240,235	239,055
Fair value reserves	2,618	2,594
Accumulated deficit	(210,632)	(202,144)
<b>Total equity</b>	<b>32,845</b>	<b>40,129</b>
<b>Non-current liabilities</b>		
Borrowings	323	1,690
Contract liabilities	39,138	37,512
Lease liabilities	246	0
<b>Total non-current liabilities</b>	<b>39,707</b>	<b>39,202</b>
<b>Current liabilities</b>		
Trade and other payables	7,541	9,425
Provisions	1,440	0
Borrowings	3,552	3,083
Lease liabilities	377	0
Contract liabilities	13,655	24,335
<b>Total current liabilities</b>	<b>26,565</b>	<b>36,843</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>99,117</b>	<b>116,174</b>

**Affimed N.V.**  
**Unaudited consolidated statements of cash flows (in € thousand)**

	For the six months ended	
	June 30	
	2019	2018
<b>Cash flow from operating activities</b>		
Income / (loss) for the period	(8,488)	(16,217)
Adjustments for the period:		
- Income taxes	4	1
- Depreciation and amortisation	423	199
- Net gain from disposal of leasehold improvements and equipment	(9)	0
- Share based payments	1,167	937
- Finance income / costs – net	(180)	(811)
	<u>(7,083)</u>	<u>(15,891)</u>
Change in trade and other receivables	228	88
Change in inventories	(70)	(26)
Change in other assets	(2,586)	(1,159)
Change in trade, other payables, provisions and contract liabilities	<u>(9,484)</u>	<u>1,970</u>
Cash used in operating activities	(18,995)	(15,018)
Interest received	188	58
Paid interest	<u>(134)</u>	<u>(196)</u>
<b>Net cash used in operating activities</b>	<b>(18,941)</b>	<b>(15,156)</b>
<b>Cash flow from investing activities</b>		
Purchase of intangible assets	(142)	(26)
Purchase of leasehold improvements and equipment	(755)	(298)
Cash received from the sale of leasehold improvements and equipment	0	1
Cash paid for investments in financial assets	(35,262)	0
Cash received from maturity of financial assets	<u>25,748</u>	<u>0</u>
<b>Net cash used for investing activities</b>	<b>(10,411)</b>	<b>(323)</b>
<b>Cash flow from financing activities</b>		
Proceeds from issue of common shares	13	25,042
Transaction costs related to issue of common shares	0	(1,686)
Proceeds from borrowings	562	0
Repayment of lease liabilities	(206)	0
Repayment of borrowings	<u>(1,649)</u>	<u>(1,500)</u>
<b>Cash flow from financing activities</b>	<b>(1,280)</b>	<b>21,856</b>
<b>Exchange-rate related changes of cash and cash equivalents</b>	<b>(210)</b>	<b>1,198</b>
<b>Net changes to cash and cash equivalents</b>	<b>(30,632)</b>	<b>6,377</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>94,829</b>	<b>39,837</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>63,987</b>	<b>47,412</b>

**Affimed N.V.**  
**Unaudited consolidated statements of changes in equity (in € thousand)**

	Issued capital	Capital reserves	Fair Value reserves	Accumulated deficit	Total equity
<b>Balance as of January 1, 2018</b>	<b>468</b>	<b>213,778</b>	<b>7,325</b>	<b>(182,667)</b>	<b>38,904</b>
Issue of common shares	156	23,190			23,346
Equity-settled share based payment awards		937			937
Loss for the period				(16,217)	(16,217)
Other comprehensive income			211		211
<b>Balance as of June 30, 2018</b>	<b>624</b>	<b>237,905</b>	<b>7,536</b>	<b>(198,884)</b>	<b>47,181</b>
<b>Balance as of January 1, 2019</b>	<b>624</b>	<b>239,055</b>	<b>2,594</b>	<b>(202,144)</b>	<b>40,129</b>
Exercise of share based payment awards		13			13
Equity-settled share based payment awards		1,167			1,167
Loss for the period				(8,488)	(8,488)
Other comprehensive income			24		24
<b>Balance as of June 30, 2019</b>	<b>624</b>	<b>240,235</b>	<b>2,618</b>	<b>(210,632)</b>	<b>32,845</b>