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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

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**FORM 20-F**

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(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

Commission file number: 001-36619

**AFFIMED N.V.**

(Exact name of Registrant as specified in its charter)

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or organization)

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, nominal value €0.01 per	AFMD	The NASDAQ Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Title of Class

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Title of Class

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Indicate the number of outstanding shares of each of the issuer’s classes of capital stock or common stock as of the close of the period covered by the annual report.

Common shares: 149,339,335

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No  
(not required)

Indicate by check mark whether the registrant is a large, accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of “large, accelerated filer,” “accelerated filer,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer  Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

†The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attention to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.  Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

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Unless otherwise indicated or the context otherwise requires, all references in this Annual Report on Form 20-F (the “Annual Report”) to “Affimed N.V.” or “Affimed,” the “Company,” “we,” “our,” “ours,” “us” or similar terms refer to Affimed N.V., together with its subsidiaries.

#### TRADEMARKS

Affimed®, ROCK® (“Redirected Optimized Cell Killing”) and ICE® (“Innate Cell Engager”) are our registered word trademarks. Moreover, combined word and figurative trademarks are registered for the Affimed logo in color and grayscale. The trademarks, trade names and service marks appearing in this Annual Report are property of their respective owners.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTOR SUMMARY

This Annual Report contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this Annual Report can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “will,” “estimate” and “potential,” among others.

Forward-looking statements appear in a number of places in this Annual Report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section “Item 3. Key Information—D. Risk factors” in this Annual Report. These risks and uncertainties include factors relating to:

- our operation as a development stage company with a history of operating losses; as of December 31, 2022, our accumulated deficit was €430.2 million;
- the possibility that our clinical trials may be delayed or put on clinical hold; for example, due to slower than expected enrollment or regulatory actions, or not be successful and clinical results may not reflect results seen in previously conducted preclinical studies and clinical trials, or expectations based on these preclinical studies and clinical trials;
- our reliance on contract manufacturers and contract research organizations over which we have limited control;
- our lack of adequate funding to complete development of our product candidates and the risk we may be unable to access additional capital on reasonable terms or at all to complete development and begin commercialization of our product candidates;
- our dependence on the success of AFM13 and AFM24 (which are still in clinical development) and certain of our other product candidates including AFM28, each of which may eventually prove to be unsuccessful or commercially not exploitable;
- the success of the Affimed-Artiva partnership, including in relation to 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 AB-101, which is a cryopreserved allogeneic cord blood-derived NK cell that we anticipate will be co-administered with AFM13;
- uncertainty surrounding whether any of our product candidates will gain regulatory approval, which is necessary before they can be commercialized;
- the outcome of any discussions we may enter regarding, acquisitions, dispositions, partnerships, license transactions or changes to our capital structure, including our receipt of any milestone payments or royalties or any future securities offerings;
- the chance that we may become exposed to costly and damaging liability claims resulting from the testing of our product candidates in the clinic or in the commercial stage;
- if our product candidates obtain regulatory approval, our being subject to expensive ongoing obligations and continued regulatory oversight;
- enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization;
- future legislation may materially impact our ability to realize revenue from any approved and commercialized products;

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- the chance that our products may not gain market acceptance, in which case we may not be able to generate product revenues;
- our reliance on our current strategic relationships with NKGen Biotech, Roivant, Artiva, The MD Anderson Cancer Center, and Genentech and the potential failure to enter into new strategic relationships or difficulties with our strategic partners that may slow the progress of our joint development or lead to the termination of a partnership and the need to enter into a new one, all of which could take substantial time and attention of our management team;
- our reliance on third parties to conduct our nonclinical and clinical trials and on third-party, single-source suppliers to supply or produce our product candidates;
- our ability to scale-up manufacturing processes of our product candidates and reduce the cost of manufacturing our product candidates in advance of commercialization;
- our future growth and ability to compete, which depends on retaining key personnel and recruiting additional qualified personnel;
- the length and severity of the COVID-19 pandemic and its impact on our business, including our supply chain, clinical trials and operations;
- the impact on our business of macroeconomic trends, political events, war, terrorism, business interruptions and other geopolitical events and uncertainties, such as the Russia-Ukraine conflict and the instability in the banking sector experienced in the first quarter of 2023; and
- other risk factors discussed under “Item 3. Key Information—D. Risk Factors.”

Our actual results or performance could differ materially from those expressed in, or implied by, any forward-looking statements relating to those matters. Accordingly, no assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do so, what impact they will have on our results of operations, cash flows or financial condition. Additionally, some of the risks and uncertainties identified above may be amplified by the COVID-19 pandemic. It is not possible to predict or identify all such risks. There may be additional risks that we consider immaterial, or which are unknown. Except as required by law, we are under no obligation, and expressly disclaim any obligation, to update, alter or otherwise revise any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

**PART I**

**ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

**A. Directors and senior management**

Not applicable.

**B. Advisers**

Not applicable.

**C. Auditors**

Not applicable.

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

**A. Offer statistics**

Not applicable.

**B. Method and expected timetable**

Not applicable.

**ITEM 3. KEY INFORMATION**

**A. [Reserved]**

**B. Capitalization and indebtedness**

Not applicable.

**C. Reasons for the offer and use of proceeds**

Not applicable.

**D. Risk factors**

*You should carefully consider the risks and uncertainties described below and the other information in this Annual Report before making an investment in our common shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common shares could decline and you could lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements and Risk Factor Summary." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.*

## Risks Related to Our Business and the Development and Commercialization of Our Product Candidates

***Our product candidates are in preclinical or clinical development. Drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.***

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, national competent authorities in Europe, including the Paul-Ehrlich-Institute or PEI in Germany, and other non-U.S. regulatory authorities, which establish regulations that differ from country to country. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a Biologics License Application, or BLA, from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates. We have limited experience in conducting and managing the clinical studies necessary to obtain regulatory approvals, including approval by the FDA or the European Commission. Obtaining approval of a BLA or a marketing authorization application can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA, EMA and other non-U.S. regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical studies, including full or partial clinical holds, or other regulatory objections to ongoing or planned trials;
- restrictions on the products, manufacturers, or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs in the United States and refusal to approve marketing authorization applications in other jurisdictions.

The FDA, the EMA and other non-U.S. regulatory authorities also have substantial discretion in the drug approval process. The number of preclinical studies and clinical studies that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- the results may not confirm the positive results from earlier preclinical studies or clinical studies;



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- regulatory agencies may not find the data from preclinical studies and clinical studies sufficient or well-controlled;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; or
- regulatory agencies may change their approval policies or adopt new regulation. For example, the FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to develop a framework for identifying candidate drugs that are appropriate to initially develop for the treatment of early metastatic disease, among other goals. It is unclear how the FDA plans to implement these goals and whether they will have an impact on specific clinical programs.

For example, during the fourth quarter of 2018, the FDA concurred with our decision to place AFM11, a T cell-engaging bispecific antibody, on clinical hold after the occurrence of serious adverse events, or SAEs, in three patients, which included a death in the ALL study and two life-threatening events in the NHL study, and formally placed the AFM11 IND application on full clinical hold. We subsequently discontinued the development of AFM11. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our share price. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product.

In addition, even if regulatory approval is granted, pricing and reimbursement may not occur due to a number of factors, including formulary restrictions and health service providers determining that the benefits of a new medicine are insufficient to support reimbursement, among others.

***Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier trials may not be predictive of future trial results. If clinical studies of our product candidates are prolonged or delayed, we may be unable to obtain the required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.***

We have a limited history of conducting large-scale or pivotal clinical studies, and no history commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing our company, developing our technology and developing AFM13, AFM24, AFM28 and our other product candidates. We have not yet demonstrated an ability to successfully complete a large-scale or pivotal clinical study, obtain marketing approval, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

If clinical studies for our product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay or restrict our receipt of any product revenue.

There have been significant developments in the highly dynamic field of immuno-oncology such as the earlier availability of product candidates or earlier approval of drugs for the same indications as our product candidates, which led us to adapt our clinical programs accordingly. For example, in the past, the marketing authorization of anti-PD-1 antibodies in Hodgkin Lymphoma, or HL, resulted in delays in clinical study initiation and/or patient recruitment for our phase 2a investigator-sponsored trial (IST) of AFM13 in HL. Certain clinical studies of our product candidates are sponsored by academic sites, which are known as investigator sponsored trials (ISTs). By definition, the financing, design, and conduct of such studies are under the responsibility of the academic site sponsor. Therefore, we have limited control over these studies and we do not have control over the timing and reporting of the data from these trials. In addition, we may have limited information about ISTs while they are being conducted, including the timing of planned trial initiation, the status of patient recruitment, changes to trial design, and clinical study results.

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In December 2022, we reported topline results from the REDIRECT study of AFM13 as monotherapy in patients with relapsed or refractory CD30 positive peripheral T cell lymphoma, or PTCL, and announced that, based on the results of REDIRECT and the comparatively more attractive clinical and commercial opportunity for AFM13 in combination with NK cells, we would not continue to pursue the development of AFM13 monotherapy in PTCL.

During 2020, we initiated a first-in-human phase 1/2a trial of AFM24 (AFM24-101), a first-in-class innate cell engager for various solid tumor indications. As we have only limited human data on AFM24 at this stage, we cannot assure you of its success. We have not previously tested our innate cell engagers in solid tumors in the clinical setting. The goals of the trial are to establish a dose for phase 2 testing as well as to evaluate the safety, tolerability and preliminary efficacy of AFM24 in patients with selected solid tumor subtypes. In the AFM24-101 monotherapy clinical trial, a weekly dose of 480 mg has been identified as the recommended phase 2 dose based on a comprehensive review of safety, pharmacokinetic and pharmacodynamic data, including exposure and NK cell CD16A receptor occupancy. For monotherapy expansion, cohorts have been initiated at the recommended phase 2 dose in the following indications: (a) renal cell carcinoma (clear cell), failing standard of care (SoC) therapy including tyrosine kinase inhibitors (TKIs) and PD1 targeted therapy; (b) non-small cell lung cancer (EGFR-mutant), failing SoC TKIs; and (c) colorectal cancer (KRAS wildtype, MSS), failing SoC chemotherapy.

Furthermore, we have initiated two separate clinical studies investigating the safety, tolerability and preliminary efficacy of AFM24 in combination with a checkpoint inhibitor or an autologous NK cell product.

We have initiated the phase 1/2a combination study of AFM24 with the PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in EGFR-expressing solid tumors. The combination trial includes the following indications: (a) non-small cell lung cancer (EGFR-wildtype), failing chemotherapy and PD1 or PD-L1 targeted therapy; (b) gastric/gastroesophageal junction (GEJ) cancer refractory to or, intolerant of, standard therapy; and (c) a basket cohort including EGFR-expressing tumors comprising pancreatic, hepatocellular and biliary tract cancer failing standard of care therapy for the respective disease.

We have initiated the phase 1/2a combination study of AFM24 with NKGen Biotech's autologous NK cell therapy, SNK01, a first-in-human proof of concept trial in EGFR-expressing solid tumors. The combination trial includes the following indications: (a) non-small cell lung cancer (EGFR-wildtype), failing chemotherapy and PD1/PD-L1 targeted therapy; (b) squamous cell carcinoma of the head and neck, failing chemotherapy and PD1/PD-L1 targeted therapy; and (c) colorectal cancer including those with RAS and BRAF mutations, failing standard of care therapy.

At this stage, we cannot assure you of the safety or tolerability of AFM24 mono- or combination therapy, or of its ability to demonstrate efficacy in humans.

The commencement of planned clinical studies could be substantially delayed or prevented by several factors, including:

- further discussions with the FDA, the EMA, or other regulatory agencies regarding the scope or design of our clinical studies;
- the limited number of, and competition for, suitable sites to conduct our clinical studies, many of which may already be engaged in other clinical study programs, including some that may be for the same indication as our product candidates;
- approval of drugs for the same indications as our product candidates;
- any delay or failure to obtain regulatory approval or agreement to commence a clinical study in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical study;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical study;

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- delay or failure in the testing, validation, manufacture and delivery of sufficient supplies of product candidate for our clinical studies;
- delays related to the impact of the COVID-19 pandemic;
- delay or failure to reach agreement on acceptable clinical study agreement terms with prospective sites or clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and
- delay or failure to obtain institutional review board, or IRB, or ethics committee approval to conduct a clinical study at a prospective site.

The completion of our clinical studies has been and could in the future be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment, due to factors including, but not limited to, the availability of other drugs to treat potential patients, the unwillingness of patients to participate in low-dose groups of dose-ranging studies and lack of recruitment by clinical study sites;
- delays relating to adding new clinical study sites;
- failure of patients to complete the clinical study or return for post-treatment follow-up;
- failure of our collaborators to provide us with products necessary for us to conduct our combination studies;
- safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- the FDA or other regulatory authorities requiring us to suspend or terminate a clinical study, or requiring us to submit additional data or imposing other requirements before permitting us to continue a clinical study;
- lack of efficacy during clinical studies;
- errors in trial design or conduct;
- termination of our clinical studies by one or more clinical study sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical study protocols, including clinical investigators' failure to comply with our clinical study protocols without our notice;
- inability to monitor patients adequately during or after treatment by us and/or our CROs; and
- the need to repeat or terminate clinical studies as a result of inconclusive or negative results or unforeseen complications in testing.

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For example, in our clinical studies for AFM13 and AFM24, infusion related reactions (IRRs) have been a commonly observed treatment-related side effect, in some cases serious. In our Phase 1b study evaluating the combination of AFM13 with pembrolizumab, IRRs related to AFM13 were observed in 27 of 30 patients, or 90%, and IRRs of grade 3 or greater were observed in four patients, or 13%. IRRs were also observed in our Phase 2 REDIRECT study evaluating AFM13 for the treatment of relapsed / refractory PTCL, our Phase 1/2a study evaluating NK cells pre-complexed with AFM13 in patients with CD30+ lymphomas, and our Phase 1/2a studies evaluating AFM24 in patients with EGFR-expressing tumors. While these IRRs have generally been well managed with pre-medication and interventional treatments, the incidence of IRRs has occasionally led to dose reductions and/or patients discontinuing their participation in our clinical trials. As we increase the number of clinical trials for our ICE<sup>®</sup> molecules and study them against new tumor targets, there can be no assurance that IRRs or other side effects will not cause delays or termination of our future clinical studies or development plans.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical study protocols or submit new clinical study protocols to reflect these changes with the appropriate regulatory authorities. In addition, changes in the competitive environment have occurred and may continue to occur.

Amendments may require us to renegotiate terms with CROs or resubmit clinical study protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical study.

Our clinical studies may be suspended or terminated at any time by the FDA, the PEI, other regulatory authorities, the IRBs or ethics committees overseeing the clinical study at issue, any of our clinical study sites, or us, due to a number of factors, including:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- safety issues or any determination that a clinical study presents unacceptable health risks;
- lack of adequate funding to continue the clinical study due to unforeseen costs or other business decisions;
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates; and
- availability of a new effective treatment for the respective disease or condition that would be considered to be standard of care by regulatory bodies.

Our product development costs will increase if we experience delays in clinical studies or marketing approvals or if we are required to conduct additional clinical studies or other testing of our product candidates. We may be required to obtain additional funding to conduct and complete such clinical studies. We cannot assure you that our clinical studies will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which may harm our business and results of operations.

Any failure or significant delay in completing clinical studies for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

***The results of previous clinical studies may not be predictive of future results, our progress in trials for one product candidate may not be indicative of progress in trials for other product candidates and the results of our current and planned clinical studies may not satisfy the requirements of the FDA, the EMA or other non-U.S. regulatory authorities.***

In addition to the risks and uncertainties discussed elsewhere in this Annual Report, the results of our previous clinical studies may not be predictive of future results, our progress in trials for one product candidate may not be indicative of progress in trials for other product candidates and the results of our current and planned clinical studies may not satisfy the requirements of the FDA, the EMA or other non-U.S. regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical studies may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical studies that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical studies will be successful, because product candidates in later-stage clinical studies may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical studies. Product candidates that have shown promising results in early clinical studies may still suffer significant setbacks in subsequent registration clinical studies. Similarly, the outcome of preclinical testing and early clinical studies may not be predictive of the success of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Progress in trials of one product candidate does not indicate that we will make similar progress in additional trials for that product candidate or in trials for our other product candidates. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical studies, even after obtaining promising results in earlier clinical studies.

In addition, the design of a clinical study can determine whether its results will support approval of a product and flaws in the design of a clinical study may not become apparent until the clinical study is well advanced. We may be unable to design and execute a clinical study to support regulatory approval.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical study participants. We do not know whether any phase 2, phase 3 or other clinical studies we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Furthermore, changes in combination therapies that we utilize in our clinical trials may create variability between results of early-stage clinical trials and later clinical trials. For example, to date we have generated data for AFM13 combined with allogeneic natural killer cells in CD30-positive lymphomas utilizing a natural killer cell product from MD Anderson Cancer Center. The natural killer cell used in the Phase 1/2 trial is a freshly prepared, cord blood-derived NK cell that is precomplexed with AFM13. In November 2022, we announced a collaboration with Artiva Biotherapeutics with the goal of advancing the development of the combination of AFM13 with Artiva's AB-101 NK cell therapy into a potential registration enabling study. While AB-101 is also an allogeneic, cord blood-derived NK cell, there are differences as compared to the cell used in our Phase 1/2 study, including the fact that AB-101 is cryopreserved and is manufactured and activated in different ways than the MD Anderson NK cell. Further, rather than precomplexing AFM13 with AB-101, we intend to co-administer AFM13 with AB-101. In January 2023, we announced that the FDA issued a written response to our pre-IND meeting request for AFM13 and AB-101 and, based on the written response, we remain on track to submit an IND in the first half of 2023 and, subject to FDA clearance of the IND, to initiate a clinical study during 2023.

Further, our product candidates may not be approved even if they achieve their primary endpoints in phase 3 clinical studies or registration trials. The FDA, the EMA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical and clinical studies. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical study. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical studies. The FDA, the EMA or other non-U.S. regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

***We depend on enrollment of patients in our clinical studies for our product candidates. We compete with other sponsors who have ongoing clinical studies of investigational therapies for patients for our clinical studies. If we are unable to enroll patients in our clinical studies, our research and development efforts could be materially adversely affected.***

Successful and timely completion of clinical studies will require that we enroll a sufficient number of patients. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical studies, the availability of new drugs approved for the indication the clinical study is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. In addition, we compete with approved immunotherapies and investigational immunotherapies for patients for our clinical studies. Our product candidate AFM13 has orphan drug designation for the treatment of HL, from FDA and EMA, and for the treatment of T-cell lymphoma from the FDA, which means that the potential patient population is limited. As we are developing AFM13 and certain of our other product candidates for patients for whom previous therapies have failed and who may not have long to live, patients may elect not to participate in our, or any, clinical study.

The approval of new immuno-oncology drugs such as checkpoint inhibitors (CPIs) has changed the landscape for conducting clinical studies of other oncology drugs, including ours, both for indications for which such drugs are approved as well as for indications in which additional trials are being conducted. In addition, there are several other types of drugs in development for the indications for which we are developing AFM13 and certain of our other product candidates. We compete for patients with the sponsors of trials for all of these drugs. These factors may make it difficult for us to enroll enough patients to complete our clinical studies in a timely and cost-effective manner.

Delays in the completion of any clinical study of our product candidates will increase our costs, prolong our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

***The COVID-19 pandemic has adversely impacted and could continue to impact our business, including our supply chain, clinical trials and operations.***

The COVID-19 pandemic has, and continues to, adversely impact clinical and preclinical trials globally and in different therapeutic areas. As a result, our clinical trials or preclinical studies, including our ability to recruit and retain patients, principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, have been, and may continue to be, significantly impacted. We have implemented mitigation procedures designed to enable us to address the various issues caused by the COVID-19 pandemic, although there can be no assurance that these procedures will be successful or that we can avoid a material and adverse disruption to our business. As the pandemic continues, we may experience the prioritization of hospital resources toward the outbreak and further restrictions on travel. Furthermore, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. For example, in January 2022, we announced that we would no longer pursue the TMF cohort in our phase 2 clinical trial evaluating AFM13 as monotherapy due to the continuing challenges to enroll patients with this indication as a result of the COVID-19 pandemic.



The COVID-19 pandemic may also negatively affect the operations of third-party contract research organizations that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, each of which could result in delays or disruptions in the supply of our product candidates. The negative impact the COVID-19 pandemic has had and may continue to have on patient enrollment and treatment, and the timing and execution of our clinical trials could cause costly delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to advance towards commercialization, increase operating expenses and have a material adverse effect on our business and financial results.

In addition, the COVID-19 pandemic has resulted in significant governmental measures being implemented to control the spread of the virus. Public health officials have recommended and mandated precautions to mitigate the spread of COVID-19, including prohibitions on congregating, traveling across borders, shelter-in-place orders and other similar measures. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring some or all of our employees to work remotely, suspending all non-essential travel and discouraging employee attendance at industry events and in-person work-related meetings. Such measures could negatively affect our business. For instance, temporarily requiring employees to work remotely may disrupt our operations or create unforeseen issues related to the use of technology designed to allow for remote communication and collaboration. The COVID-19 pandemic has also caused volatility in the global financial markets and has threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The COVID-19 pandemic is ongoing, in large part due to the prevalence of new variants of the SARS-CoV-2 virus, and, accordingly, we may continue to experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials. The full extent to which the COVID-19 pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted at this time. As such, we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, the impacts on our business, financing or clinical trial activities or on the healthcare system and the global economy as a whole.

***Our business may be impacted by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control.***

War, terrorism, geopolitical uncertainties, and other business interruptions could cause damage to or disrupt our operations and those of our third-party suppliers, partners, and collaborators. In addition, territorial invasions can lead to cybersecurity attacks located far outside of the conflict zone. Interruptions to our operations could seriously harm our ability to timely proceed with any clinical programs, and could imply incurring in significant expenditures as salaries and loan payments would usually continue. Following Russia's invasion of Ukraine in February 2022, the U.S., several European Union nations, and other countries have announced sanctions against Russia, and the North Atlantic Treaty Organization (NATO) has deployed additional military forces to Eastern Europe. The invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by Russia, the U.S., NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain, adversely affect our ability to conduct ongoing and future clinical trials of our product candidates, and adversely affect our ability to commercialize our products (subject to regulatory approval).

***We use new technologies in the development of our product candidates and the FDA and other regulatory authorities have not approved products that utilize these technologies.***

Our innate cell engager product candidates in development are based on our fit-for-purpose ROCK® (“Redirected Optimized Cell Killing”) platform and are capable of recruiting NK cells and / or macrophages. Regulatory approval of our product candidates is less certain than the approval of drugs that do not employ such novel technologies or methods of action. We intend to work closely with the FDA, the EMA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. For example, final assays and specifications of our product candidates have yet to be developed, and the FDA, EMA or other regulatory authorities may require additional analyses to evaluate different aspects of our product quality. It is possible that the validation process may take time and resources, may require independent third-party analyses, or may not be accepted by the FDA, the EMA or other regulatory authorities. Delays or failure to obtain regulatory approval of any of the product candidates that we are developing would adversely affect our business.

***Even if our product candidates obtain regulatory approval, they will be subject to continuous regulatory review.***

If marketing authorization is obtained for any of our product candidates, the product will remain subject to continuous review and therefore authorization could be subsequently withdrawn or restricted. We will be subject to ongoing obligations and oversight by regulatory authorities, including adverse event reporting requirements, marketing restrictions and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical studies, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

***We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.***

A key element of our strategy is to use and expand our technology platforms to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

***Even if we obtain marketing approval of any of our product candidates in a major pharmaceutical market such as the United States or Europe, we may never obtain approval or commercialize our products in other major markets, which would limit our ability to realize their full market potential.***

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical studies which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.



***In the United States, we may seek fast track designation of AFM13 and certain of our other product candidates, with the intent to pursue an accelerated approval pathway and potentially, breakthrough designation of AFM13 and/or certain of our other product candidates. There is no assurance that the FDA will grant such designations; and, even if it does grant such designations to AFM13 and/or certain of our other product candidates, such designation may not actually lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval in the United States.***

Based on clinical data, either from ongoing or new clinical studies, we plan to seek fast track designation of AFM13 as a combination therapy in relevant indications. In addition, we may seek fast-track designation of certain of our other product candidates. The fast track program, a provision of the FDA Modernization Act of 1997, is designed to facilitate interactions between a sponsoring company and the FDA before and during submission of a BLA for an investigational agent that, alone or in combination with one or more other drugs, is intended to treat a serious or life-threatening disease or condition, and which demonstrates the potential to address an unmet medical need for that disease or condition. Under the fast track program, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application if the FDA determines, after a preliminary evaluation of the clinical data, that a product that has been granted fast track designation may be effective. A fast track designation provides the opportunity for more frequent interactions with the FDA, and a product that has been granted fast track designation could be eligible for priority review if supported by clinical data at the time of submission of the BLA.

The FDA is authorized to designate a product candidate as a breakthrough therapy if it finds that the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA can also be eligible for accelerated approval if the relevant criteria are met.

The FDA has broad discretion on whether or not to grant fast track or breakthrough designation. Accordingly, even if we believe one of our product candidates meets the criteria for fast track or breakthrough designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of fast-track or breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as fast track or breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***We may be unable to obtain orphan product designation or exclusivity for some of our product candidates. If our competitors are able to obtain orphan product exclusivity for their products in the same indications for which we are developing our product candidates, we may not be able to have our products approved by the applicable regulatory authority for a significant period of time. Conversely, if we obtain orphan drug exclusivity for some of our product candidates, we may not be able to benefit from the associated marketing exclusivity.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the European Union, or the EU, the European Commission may designate a product candidate as an orphan medicinal product if it is a medicine for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect not more than five in 10,000 persons in the European Union, or it is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. We have received orphan drug designation for AFM13 for the treatment of HL in the United States and Europe, and for T-cell lymphoma in the United States; but orphan drug status does not ensure that we will have market exclusivity in a particular market and there is no assurance we will be able to receive orphan drug designation for certain of our other product candidates or any additional product candidates. Further, the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which, subject to certain exceptions, precludes the FDA from approving the marketing application of the same drug from another sponsor for the same indication for that time period or precludes the EMA, and other national drug regulators in the EU, from accepting the marketing application for a similar product from another sponsor for the same indication. The applicable period is seven years in the United States and ten years in the European Union. The EU period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. In the EU, orphan exclusivity may also be extended for an additional two years (*i.e.*, a maximum of 12 years orphan exclusivity) if the product is approved on the basis of a dossier that includes pediatric clinical study data generated in accordance with an approved pediatric investigation plan. Orphan drug exclusivity may be lost in the United States if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for one or more of our products that exclusivity may not effectively protect the product from competition because exclusivity can be suspended under certain circumstances. In the United States, even after an orphan drug is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, orphan exclusivity will not prevent a marketing authorization being granted for a similar medicinal product in the same indication if the new product is safer, more effective or otherwise clinically superior to the first product or if the marketing authorization holder of the first product is unable to supply sufficient quantities of the product.

***Our product candidates may result in serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.***

Although all of our product candidates have undergone or will undergo safety testing to the extent possible and agreed with health authorities, not all adverse effects of drugs can be predicted or anticipated. Immunotherapy and its mode of action of harnessing the body's immune system, especially with respect to immune cell engagers, is powerful and could lead to serious side effects that we only discover in clinical studies. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if such side effects are rarer, after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. All of our product candidates are still in clinical or preclinical development. While our phase 1 clinical studies for AFM13 demonstrated a favorable safety profile, the results from ongoing and future trials of AFM13 or other NK cell-engaging bispecific antibodies may not confirm these results. The most frequently observed adverse event for AFM13 is infusion related reactions (IRRs), in some cases serious. In our Phase 1b study evaluating the combination of AFM13 with pembrolizumab, IRRs related to AFM13 were observed in 27 of 30 patients, or 90%, and IRRs of grade 3 or greater were observed in four patients. IRRs were also observed in our Phase 2 study evaluating AFM13 for the treatment of relapsed / refractory PTCL, our Phase 1/2a study evaluating NK cells pre-complexed with AFM13 in patients with CD30+ lymphomas, and our Phase 1/2a studies evaluating AFM24 in patients with EGFR-expressing tumors. While these IRRs have generally been well managed with pre-medication and interventional treatments, the incidence of IRRs has occasionally led to dose reductions and/or patients discontinuing their participation in our clinical trials. As we increase the number of clinical trials for our ICE<sup>®</sup> molecules and study them against new tumor targets, there can be no assurance that IRRs or other side effects will not cause delays or termination of our future clinical studies or development plans.

We are developing our AFM13 product candidate for patients with relapsed or refractory HL and other CD30+ lymphomas, and AFM24 for patients with EGFR+ solid tumor indications, for which other therapies have limited benefit and survival times may be short. Therefore, we expect that certain patients may die during the clinical studies of our product candidates, and it may be difficult to ascertain whether such deaths are attributable to the underlying disease, complications from the disease, our product candidate, or a combination thereof.

The results of ongoing and future clinical studies may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical studies, and result in the delay of, or failure to obtain, marketing approval from the FDA, the European Commission and other regulatory authorities, or result in marketing approval from the FDA, the European Commission and other regulatory authorities with restrictive label warnings or potential product liability claims. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the study, or make the product candidate less attractive for partnering. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, particularly outside of our existing or future collaborators as toxicities resulting from cancer immunotherapies are not normally encountered in the general patient population and by medical personnel. The inability to recognize and manage the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product;

- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

***Adverse events in the field of immuno-oncology could damage public perception of our product candidates and negatively affect our business.***

The commercial success of our products will depend in part on public acceptance of the use of cancer immunotherapies. SAEs and other adverse events in clinical studies of our product candidates or in clinical studies of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for any products that we may develop. Although the mode of action of our innate cell engagers differs from that of other immuno-oncology approaches in development, the public may not always differentiate between our therapies and others in the field. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, our products may not be accepted by the general public or the medical community.

Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

***Even if approved, if any of our product candidates do not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, our revenue generated from their sales will be limited.***

The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;

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- the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line, second-line, third-line, or subsequent line of therapy for particular diseases;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- confirmation of the safety and effectiveness of the product candidate in a real-world clinical setting;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

***We are subject to manufacturing risks that could substantially increase our costs and limit supply of our products or prevent us from achieving a commercially viable production process.***

The process of manufacturing our products is complex, highly regulated and subject to several risks, including:

- We do not have experience in manufacturing our product candidates at commercial scale. We contract with external manufacturers to develop a larger scale manufacturing process for AFM13 in order to have material supply available for the registration directed phase 2b trial. We may not succeed in scaling up the process to commercial scale. We may need a larger scale manufacturing process for certain of our product candidates than what we have planned, depending on the dose and regimen. Any changes in our manufacturing processes as a result of scaling up may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals as a result of scaling up could delay the development and regulatory approval of our product candidates and ultimately affect our success.
- We may not achieve the manufacturing productivity, or yield, required to achieve a commercially viable cost of goods. Our molecules are novel antibody structures and there is very limited knowledge as to which productivities can be achieved at commercial scale. Low productivity may result in a cost of goods which is too high to allow profitable commercialization, or give rise to the need for additional manufacturing process optimization which would require additional funding and time.
- The process of manufacturing biologics, such as AFM13, AFM24 and AFM28, certain of our other product candidates and the NK cells we use for our combination studies, is susceptible to product loss due to contamination, improper storage or shipping conditions, equipment failure or improper installation or operation of equipment, vendor or operator error, and difficulties in scaling up the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination.
- In addition, the clinical development of our product candidates in combination with NK cells depends on the availability of certain materials and agents that are used in the production of NK cells or in our clinical trials. For example, certain of our clinical trial protocols for combinations with NK cells require the use of cyclophosphamide and fludarabine, agents which are routinely used in oncology studies to condition patients for treatment with NK cells. Recently, the FDA has reported a shortage of fludarabine, and some clinical trial sites may in the future institute enrollment holds or halt

enrollment of patients if sufficient quantities of fludarabine cannot be secured. We cannot predict the extent and duration of this shortage of fludarabine, although any failure or delays by us or by our clinical sites to obtain sufficient quantities of fludarabine, or other components and agents necessary for the manufacturing of NK cells or the conduct of our clinical trials, may delay our ability to enroll and treat patients in, or complete, our current or future clinical trials in combination with NK cells on time, if at all.

- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, health epidemics, power failures and numerous other factors.
- We must comply with applicable current Good Manufacturing Practice, or cGMP, regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. We are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, leading to significant delays in the availability of drug product for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.
- Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.
- Our product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical studies or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates.

***We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, or if we fail to achieve adequate pricing and/or reimbursement we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales and distribution capabilities because our lead product candidates are still in clinical development. If any of our product candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, or to outsource this function to a third party. Either of these options would be expensive and time consuming. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products,



either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We may not be able to achieve the prices for our products that we may need for sustained profitability. In particular, there are different and changing reimbursement regulations in major market countries and other countries, and we might not be able to show the specific benefit or other requirements required for reimbursement or reimbursement at a specified pricing level in one or more jurisdictions.

In addition, if we successfully develop combinations of our product candidates with other potentially expensive agents, the market may not allow premium pricing of our products and hence may impair our ability to achieve profitability.

***We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.***

The life sciences industry is highly competitive and subject to rapid and significant technological change. We are currently developing therapeutics that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in discovering, developing, obtaining patent protection, marketing approval and commercialize products in our field before we do.

There are many companies developing or marketing treatments for cancer disorders, including many major pharmaceutical and biotechnology companies. These treatments consist of small molecule drug products, biologic therapeutics that work either by using next-generation antibody technology platforms or new immunological approaches to address specific cancer targets, as well as genetically engineered cellular therapeutics. These treatments are often combined with one another in an attempt to maximize efficacy. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule, as we are.

Clinical phase 2 data with the anti-PD-1 CPis nivolumab and pembrolizumab in HL have been published, as has pembrolizumab Phase 3 data. These data indicate that treatment with anti-PD-1 antibodies results in high response rates in the salvage setting of HL. In 2016, the FDA granted accelerated approval, and the European Commission granted approval for nivolumab in classical HL patients who have relapsed or progressed after autologous hematopoietic stem cell transplantation and brentuximab vedotin (Adcetris®). In 2017, the FDA granted accelerated approval, and the European Commission granted approval for pembrolizumab in adult and pediatric patients with refractory cHL who have relapsed after 3 or more prior lines of therapy, and the European Commission granted approval for pembrolizumab in adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin. In 2020, the FDA approved an expanded label for pembrolizumab in relapsed or refractory cHL. Phase 2 and phase 3 studies of brentuximab vedotin in combination with nivolumab are either planned or ongoing. If AFM13, in combination with NK cell therapy, were to be approved for HL, we could be in competition with these therapies, as well as any other therapies or combination regimens that comprise the standard of care that our offering could potentially displace. Brentuximab vedotin, or Adcetris®, an antibody-drug conjugate targeting CD30, was approved by the FDA in relapsed/refractory HL in 2011. In addition, Adcetris® was approved by the FDA in 2018 for the treatment of previously untreated Stage 3/4 cHL in combination with chemotherapy. In the European Union, Adcetris® is approved for similar indications. Adcetris® is also indicated for previously treated systemic anaplastic large cell lymphoma (ALCL), primary cutaneous ALCL, and CD30 positive mycosis fungoides, as well as for previously untreated systemic ALCL or other CD30 positive peripheral T-cell lymphomas in combination with chemotherapy in the US and for previously

untreated systemic ALCL in Europe. Adcetris® is currently being investigated in various combinations in HL, including checkpoint inhibitors.

In late 2021, clinical data from an open label Phase 2 study of COPIKTRA® (duvelisib) in relapsed/refractory (R/R) PTCL was presented at the annual meeting of the American Society of Hematology. Both overall response and complete response rates were above that seen for other R/R PTCL agents at similar stages of development or with accelerated approval. On the strength of this data, duvelisib was added to the National Comprehensive Cancer Network treatment guidelines as a “Category 2a: Other Recommended Regimen” for PTCL, Initial Palliative Intent Therapy and for PTCL, Second-Line Therapy and Subsequent Therapy, for all PTCL subtypes. COPIKTRA® (duvelisib) is currently approved for Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL). In 2022, the FDA issued a warning that clinical trial results show a possible increase in risk of death from COPIKTRA. In 2023, the EMA granted an Orphan Drug Designation for duvelisib in PTCL in Europe. If AFM13, alone or in combination is approved for PTCL patients, we could be in competition with this and any other therapies or combination regimens that comprise the standard of care that our therapy could potentially displace.

We expect that our ROCK® platform as well as our novel antibody formats derived from this platform will serve as the basis for future product candidates and collaborations with pharmaceutical companies. Other companies have also developed platform technologies that compete with our platforms. For example, Dragonfly Therapeutics is developing TriNKET, which specifically activates cells of the innate and adaptive immune system and has recently started clinical development of one of these TriNKET assets. GT Biopharma is developing its TriKEs and TetraKEs platform designed to target natural killer cells and tumor cells forming an immune synapse between the NK cell and the tumor cell thereby inducing NK cell activation at that site, and recently started its clinical development. Innate Pharma is developing several multi-specific NK cell engagers for oncology indications based on their ANKET platform. Cytovia is developing FLEX-NK bispecific antibodies to direct NK cells towards tumor targets. Furthermore, there may be other companies we have not identified that develop technologies that also engage NK cells in oncology, which would put them into competition with our therapies. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, European Commission or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

In addition, our ability to compete in the future may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. In March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA also created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product,” without the need to submit a full package of preclinical and clinical data. Under this new statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for each reference product may be reduced to seven years.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is



characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

***Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set. The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.***

In the United States, the European Union, and its respective member states and other foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system. These changes could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to sell profitably any products for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. If we successfully develop combinations of our product candidates with other potentially expensive agents, we may not achieve premium pricing for our products, which may impair our ability to achieve profitability. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In addition, the ACA, among other things, increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established a new Medicare Part D coverage gap discount program, in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were enacted, which may affect our business practices with health care practitioners. The goal of the ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory approval.

Additionally, the Drug Supply Chain Security Act, enacted in 2013, imposed new obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

In recent years, members of Congress and the former Trump Administration considered legislation to fundamentally change or repeal the ACA. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act ("TCJA") includes a provision repealing the individual insurance coverage mandate included in the ACA, effective January 1, 2019. Congress may consider other legislation to replace elements of the ACA. The implications of the ACA, its possible repeal, any legislation that may be proposed to replace the ACA, or the political uncertainty surrounding any repeal or replacement legislation for our business and financial condition, if any, are not yet clear.

Most recently, in August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

We anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system. Additionally, any new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations.***

Our business is subject to risks associated with conducting business internationally. A number of our suppliers and collaborative and clinical study relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics (See “— COVID-19 could adversely impact our business, including our supply chain, clinical trials and operations.”) or natural disasters including earthquakes, typhoons, floods and fires.

#### **Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.***

We are a clinical-stage immuno-oncology company. We have incurred significant losses since our inception. As of December 31, 2022, our accumulated deficit was €430.2 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' equity and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the FDA or the EMA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical studies or in the development of any of our product candidates.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and clinical development of our product candidates, including successfully completing registration clinical studies of AFM13 or certain of our other product candidates;
- obtaining marketing approvals for our product candidates, including AFM13 or AFM24, for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for any approved product candidates and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain marketing approval, either directly or with a collaborator or distributor;
- establishing sales, marketing, and distribution capabilities in the United States, and potentially other major markets;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;

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- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Because of the numerous risks and uncertainties of pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.***

We are advancing our product candidates through clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical studies, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical studies for each indication for each of our product candidates. We will require additional funding to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates, and such funding may not be available or acceptable due to factors beyond our control, such as rising interest rates, uncertainty in financial markets, or economic instability, and our failure to raise capital when needed could harm our business. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, assuming all of our programs advance as currently contemplated, we anticipate that our existing liquidity will enable us to fund our operating expenses and capital expenditure requirements into 2025. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of other product candidates that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development, and clinical studies;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing our product candidates and establishing sales, marketing, and distribution capabilities;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the extent to which we acquire or in-license other products or technologies;
- our need and ability to hire additional management, scientific, and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;

- the amount and timing of revenues, if any, we receive from commercial sales of any product candidates for which we receive marketing approval in the future;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing collaborations, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of achievement of milestones and receipt of any milestone or royalty payments under these agreements.

Until we can generate sufficient product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public or private equity offerings, debt financings, strategic collaborations, and grant funding. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations or even go bankrupt.

***Raising additional capital may dilute our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.***

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and licenses and development agreements in connection with any collaborations. We do not have any committed external source of funds. In the event we need to seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, our shareholders' ownership interests will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect our shareholders' rights as holders of our common shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

On January 8, 2021, we entered into a term loan agreement with Silicon Valley Bank German Branch, as lender. The loan agreement provides us with loans of up to €25.0 million available in three tranches: €10 million available at closing, an additional €7.5 million upon the achievement of certain conditions, including milestones related to our pipeline and market capitalization, and a third tranche of €7.5 million upon the achievement of certain additional conditions related to our pipeline and liquidity. The first tranche of €10 million was drawn in February 2021 and the second tranche of €7.5 million was drawn in December 2021. The third tranche of €7.5 million expired undrawn at the end of 2022. The loans will mature at the end of November 2025.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We have broad discretion in the use of our cash on hand and may not use it effectively.***

As of December 31, 2022, we had €190.3 million in cash and cash equivalents, with an anticipated cash runway into 2025. Our management will have broad discretion in the use of such funds and could spend them in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

***Our ability to use our net operating loss carry forwards and other tax attributes may be limited.***

Our ability to utilize our net operating losses, or NOLs, is currently limited, and may be limited further, under Section 8c of the *Körperschaftsteuergesetz* (the German Corporation Income Tax Act) and Section 10a of the *Gewerbsteuergesetz* (the German Trade Tax Act). These limitations apply if a qualified ownership change, as defined by Section 8c of the *Körperschaftsteuergesetz*, occurs and no exemption is applicable. Generally, a qualified ownership change occurs if more than 50% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of an increase in capital leading to a respective change in the shareholding. In the case of such qualified ownership change all tax losses and tax loss carry forwards available as of the time of the ownership change, cannot be utilized in the future. However, to the extent that the tax losses and tax loss carry forwards do not exceed hidden reserves taxable in Germany or the qualified ownership change is made for purposes of the Company's restructuring (*zum Zwecke der Sanierung*), they may be further utilized despite a qualified ownership change. Furthermore, Section 8c of the *Körperschaftsteuergesetz* is—under strict requirements—not applicable to a company provided that such company continues only those operations which are causing the loss (Section 8d *Körperschaftsteuergesetz*). In addition, the question whether the aforementioned described provisions of Section 8c of the *Körperschaftsteuergesetz* do comply with the German constitution is currently pending with the *Bundesverfassungsgericht* (German Supreme Court). On March 29, 2017, the German Supreme Court ruled that Section 8c of the *Körperschaftsteuergesetz* has not complied with the German constitution to the extent it formerly stated that a harmful ownership change should occur partially if more than 25% but less than 50% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. As a consequence of this decision, the German legislator abolished that part of the provision.

As of December 31, 2022, we had estimated NOL carry forwards for German tax purposes of approximately €372 million. Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c *Körperschaftsteuergesetz* or a Section 10a *Gewerbsteuergesetz* limitation. Any limitation may result in the expiration of a portion or the complete tax loss carry forwards before they can be utilized. As a result, if we earn net taxable income, our ability to use our pre-change NOL carry forwards to reduce German income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

***Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners' critical information technology systems or infrastructure.***

In the ordinary course of business, we and our business partners store sensitive data, including intellectual property and proprietary information related to our business and our business partners, on our information technology systems. We and certain of our service providers are from time to time subject to cyberattack attempts or incidents and security incidents. To mitigate risks we have made a substantial investment in cyber security and information security.

Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication, electrical and other system failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, intentional theft of confidential information or reputational damage, including damage to key customer and partner relationships, from system failures, espionage attacks, malware, ransomware or other cyber-attacks. Such cyber-security breaches may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. In particular, system failures or cyber-security breaches could result in the loss of nonclinical or clinical trial data from completed, ongoing or planned trials, which could cause delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The risk of a security breach or disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.



To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, we could be subject to legal claims or proceedings, liability under laws and regulations governing the protection of health and other personally identifiable information and related regulatory penalties. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

#### **Risks Related to Our Dependence on Third Parties**

***Our existing collaborations on research and development candidates are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, if these collaborations are not successful or if we fail to enter into new strategic relationships, our business could be adversely affected.***

We have entered into collaborations with other companies that we believe have provided us with valuable funding or other resources such as access to technologies, including our collaborations with Artiva, The Leukemia & Lymphoma Society, Genentech, The MD Anderson Cancer Center and Roivant Sciences. In the future, we may enter into additional collaborations to leverage our technology platforms, fund our research and development programs or to gain access to sales, marketing or distribution capabilities. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study or abandon a product candidate, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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If our collaborations on research and development candidates do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology platforms and product candidates could be delayed and we may need additional resources to develop product candidates and our technology platforms.

All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our program collaborators. Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators.

For some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical studies, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. Negotiation and diligence of potential partnerships, collaborations and alliances could require diversion of significant business resources, which could adversely impact our business operations. Furthermore, these negotiations and diligences may not eventually result in a signed agreement.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Subject to certain specified exceptions, our former collaboration with Amphivena contains restrictions on our engaging in activities that were the subject of the collaboration with third parties for specified periods of time. These restrictions survived the expiration of the agreement in July 2016.



***CROs and independent clinical investigators that we engage to conduct our clinical studies may not devote sufficient time or attention to our clinical studies or be able to repeat their past success.***

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical studies. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing the performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical studies. In addition, certain clinical studies in which we are involved and which are testing our product candidates are sponsored by academic sites, known as investigator-sponsored study, or ISTs. By definition, the financing, design, and conduct of the clinical study are under the sole responsibility of the respective sponsor. Therefore, we have limited control over these clinical studies and we do not have control over the timing and reporting of the data from these trials. In addition, we may have limited information about ISTs while they are being conducted, including the status of trial initiation and patient recruitment, changes to trial design and clinical study results. The AFM13 phase 2a study in HL and the phase 1b/2a study in CD30+ lymphoma with cutaneous manifestations were ISTs. An additional AFM13 phase 1/2 IST is currently conducted by The MD Anderson Cancer Center with CD30+ lymphoma patients. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the completion of trials of our product candidates as well as the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as current Good Clinical Practice, or GCP, and other local legal requirements, e.g., data privacy, for conducting, recording and reporting clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with GCP procedures or other applicable legal requirements could adversely affect the clinical development of our product candidates and harm our business.

***We contract with third parties for the manufacture of our product candidates for clinical testing in mono- and combination therapy settings and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, or compounds of such third parties, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We anticipate continuing our engagement of contract manufacturing organizations to provide our clinical supply as we advance our product candidates into and through clinical development. We expect to use third parties for the manufacture of our product candidates for clinical testing, as well as for commercial manufacture. We plan to eventually enter into long-term supply agreements with several manufacturers for commercial supplies. We may be unable to reach agreement on satisfactory terms with contract manufacturers to manufacture our product candidates.

Additionally, the facilities that manufacture our product candidates must be the subject of a satisfactory inspection before the FDA, the EMA or other regulatory authorities approve a BLA or grant a marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturing partners for compliance with the FDA's and the EMA's requirements for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA, European Commission and other regulatory authorities' cGMP requirements, our product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possibility of termination or nonrenewal of agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer; and
- the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA, the EMA or any other relevant regulatory authorities.

If we wish to pursue further development of AFM13, AFM24, AFM28 or any of our other ICE<sup>®</sup> molecules in combination with pembrolizumab, atezolizumab or any other CPI, we will need to reach an agreement with Merck, Roche or another partner for such supply of pembrolizumab, atezolizumab or another CPI, respectively. In addition, we are currently dependent on collaborators, such as MD Anderson, NKGen Biotech (formerly known as NKMax America) and Artiva, for the supply of NK cells for clinical and preclinical studies that evaluate our ICE<sup>®</sup> molecules in combination with NK cells. If we do not have an adequate supply and/or cannot reach an agreement with the applicable partner, we may not be able to develop AFM13, AFM24, AFM28 or any of our other ICE<sup>®</sup> molecules in any such combination. Any future supply agreement with a partner for combination trials with our ICE<sup>®</sup> molecules could influence our clinical development strategy or our intellectual property or our economic rights, and therefore might impact the content we can derive from such clinical development.

### **Risks Related to Our Intellectual Property**

***If we are unable to obtain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.***

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of non-U.S. countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States and Europe. Because patent applications in the United States, Europe and many other non-U.S. jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States, Europe and in other non-U.S. countries cannot be predicted with certainty; as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

We own and/or control our AFM13 patent portfolio, which includes three patent families. The first patent family relates to the mode of action of AFM13, the recruitment of immune effector cells via a specific receptor, i.e., an antibody or antigen-binding fragment thereof having the CDRs of AFM13. These patents will expire in 2026 in Europe and in 2029 in the US. A second patent family on AFM13 claims the method for the production of AFM13 and the product produced by this method and respective issued patents will expire in 2040. A further patent application on AFM13 relating to its combination with anti-PD1 antibodies was filed in 2016. The already granted European and Japan patent will expire in 2036 as all other patents issued on still pending applications in this family. Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g. AFM13 and the respective issued patents will not expire before 2039. A patent family is jointly owned and/or controlled with Artiva and is directed to the combination of AFM13 with Artiva's NK cell line AB-101 and respective possibly issued patents will not expire before 2042.

Moreover, we own and/or control our AFM24 patent portfolio, which includes one patent family directed to the compound of AFM24. The non-provisional patent application was filed in 2019 and issued patents will not expire before 2039. Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g. AFM24 and the respective issued patents will not expire before 2039.

For AFM28 we own and/or control a patent portfolio that includes one patent family directed to AFM28. The non-provisional patent application was filed in 2022 and issued patents will not expire before 2042. Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g. AFM28 and the respective issued patents will not expire before 2039, and the antibody scaffold of AFM28 is further protected by a patent family owned and controlled by Affimed with the respective granted patents not expiring before 2039.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous, or we may financially not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to, or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations for which legal principles remain unsolved. The standards which the United States Patent and Trademark Office, or USPTO, and its non-U.S. counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some non-U.S. countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these non-U.S. countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, and/or re-examination proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. We develop product candidates with various technologies to which third parties could obtain or have obtained proprietary rights. Our failure to obtain a license to any third-party technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we could be exposed to the threat of litigation if we fail to obtain or maintain any such license that we require.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position; an inter parties review (IPR), post grant review (PGR) of our patents may result in invalidation of some or all of the claims in any one or more of our patents; a derivation proceeding may be instituted to determine whether or not one or more of our inventions was derived from a third-party inventor;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceedings could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires showing clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

***The patent protection and patent prosecution for some of our product candidates is dependent on third parties.***

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by our licensors. Although we monitor the ongoing prosecution and maintenance of the licensed patents, if any of our future licensing partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering AFM13, AFM24, AFM28 or any of our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, selling, offering for sale or importing competing products.

***Our business may be adversely affected if we are unable to gain access to relevant intellectual property rights of third parties, or if our licensing partners terminate our rights in certain technologies that are licensed or sublicensed to us.***

We currently rely, and may in the future rely, on certain intellectual property rights licensed from third parties in order to be able to use various proprietary technologies that are material to our business.

In some cases, we do not control the prosecution, maintenance or filing of the patents to which we hold licenses, and the enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents is subject to the control or cooperation of our licensors. We cannot be certain that our licensors will prosecute, maintain, enforce and defend the licensed patent rights in a manner consistent with the best interests of our business. We also cannot be certain that drafting or prosecution of the licensed patents by our licensors have been conducted in compliance with applicable laws and regulations and will result in valid and enforceable patents and other intellectual property rights.

We are a party to a number of agreements, including license agreements, through which we have gained rights to certain intellectual property that relate to our business and we expect to enter into additional such agreements in the future. We expect that future agreements will impose various diligence, commercialization, milestone payment, royalty, and other obligations on us. Certain of our licenses contain provisions that allow the licensor to terminate the license upon the occurrence of specific events or conditions. For example, our rights under each of the licenses described above are subject to our continued compliance with the terms of the licenses, certain diligence and development obligations, the payment of royalties, milestone payments and other fees, and certain disclosure and confidentiality obligations. If we are found to be in breach of any of our license agreements, in certain circumstances our licensors may take action against us, including by terminating the applicable license. Because of the complexity of our product candidates and the patents we have licensed, determining the scope of the licenses and related obligations may be difficult and could lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license or a termination of the license. If any of our licensors were to terminate our license agreement with them, we may be prevented from the continued use of certain technologies, in clinical studies or, if our products are approved for marketing, from using such technologies in the manufacturing of products that could be sold commercially. This could delay or prevent us from offering our product candidates. We might not have the necessary rights or the financial resources to develop, manufacture or market our current or future product candidates without the rights granted under these licenses, and the loss of sales or potential sales in such product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Under certain of our agreements, our licensors have the right to convert an exclusive license to a non-exclusive license upon the expiration of the initial exclusivity period or upon the occurrence of certain events. Such a conversion would potentially allow third parties to practice the technologies licensed under the agreement and could materially adversely affect the value of the product candidate we are developing under the agreement.

In addition to the above risks, certain of our intellectual property rights are sublicenses under intellectual property owned by third parties. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements.

***If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, to the extent a confidentiality obligation is not covered by their employment agreements, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties and the public domain, so that it cannot be used for patent protection anymore, either by local law or if not applicable pursuant to specific agreements with employees and our personnel policies it is intended that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may or may not comply with their terms or with local law. Thus, despite such legal provisions or agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these legal provisions or agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not an Affirmed employee and thus not obligated to assign rights in intellectual property to us and is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in our defense, litigation could result in substantial costs and be a distraction to management.



***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various non-U.S. patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel/patent annuity service provider to pay these fees when due. Additionally, the USPTO and various non-U.S. patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

***Certain of our employees and patents are subject to German law.***

Approximately 172 of our personnel, including certain of our managing directors and most of our employees working in research and development, work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees are subject to the provisions of the German Act on Employees' Inventions (*Arbeitnehmererfindungsgesetz*), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes may occur between us and our employees or ex-employees pertaining to the sufficiency of compensation paid by us, allocation of rights to inventions under this act or alleged non-adherence to the provisions of this act, any of which may be costly to resolve and take up our management's time and efforts whether we prevail or fail in such dispute.

***If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and one or more of EU patents may be eligible for extension for up to five years under similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process and certain EU Regulations provide a Supplementary Protection Certificate ("SPC") that confers the same rights as conferred by the patent protecting the product. However, we may not receive an extension or SPC if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension or SPC could be less than we request. If we are unable to obtain patent term extension or an SPC or the term of any such extension or SPC is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Even after they have been issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition or re-examination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- the U.S. Patent and Trademark Office may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.



***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

We currently have rights to intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and non-U.S. academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable product candidate or program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States and Europe. In addition, the laws of some countries outside the United States and Europe, such as China, do not protect intellectual property rights to the same extent as federal and state laws in the United States and laws in Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and Europe, or from selling or importing products made using our inventions in and into the United States, Europe or other jurisdictions. As part of ordinary course prosecution and maintenance activities, we determine whether and in which countries to seek patent protection outside the United States and Europe. This also applies to patents we have acquired or in-licensed from third parties. In some cases, this means that we, or our predecessors in interest or licensors of patents within our portfolio, have sought patent protection in a limited number of countries for patents covering our product candidates. Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions outside the United States and Europe. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, the reproduction of our manufacturing or other know-how or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in jurisdictions outside the United States and Europe, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Our information technology systems could face serious disruptions that could adversely affect our business.***

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions in our collaborations with our partners and delays in our research and development work.

**Risks Related to Legal Compliance Matters**

***Because we and our suppliers are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.***

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

The third parties with whom we contract to manufacture our product candidates are also subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or in certain circumstances, an interruption in operations, any of which could adversely impact our business and financial condition if we are unable to find an alternate supplier in a timely manner.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, to provide accurate information to the FDA or the EMA or intentional failures to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Compliance Management System (comprising a code of conduct, a code of conduct for Business Partners, several other compliance policies, a third party due diligence process for a comprehensive background check of our key vendors and a whistleblowing hotline) which is based on three pillars: prevent, detect and respond to misconduct and an insider trading policy, each of which is communicated on a regular basis. However, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***We are subject to governmental regulation and other legal obligations in the EU and European Economic Area, or EEA, related to privacy, data protection and data security. Our actual or perceived failure to comply with such obligations could harm our business.***

We are subject to diverse laws and regulations relating to data privacy and security in the EU and eventually in the EEA, including Regulation 2016/679, known as the GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for controllers and processors of personal data. Additionally, virtually every jurisdiction in which we conduct clinical trials has established its own data security and privacy frameworks with which we must comply. New global privacy rules are being enacted and existing ones are being updated and strengthened. We are likely to be required to expend capital and other resources to ensure ongoing compliance with these laws and regulations.

Complying with these numerous, complex and often changing regulations is expensive and difficult. Failure by us, any partners, our service providers, or our employees or contractors to comply with the GDPR could result in regulatory investigations, enforcement notices and/or fines of up to the greater of €20 million or 4% of our total worldwide annual revenue. In addition to the foregoing, a breach of privacy laws or data security laws, particularly those resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition.

As a data controller, we are accountable for any third-party service providers we engage to process personal data on our behalf, including our clinical research organizations, or CROs. We attempt to mitigate the associated risks by performing security assessments and due diligence of our vendors and requiring all such third-party providers with data access to sign agreements and obligating them to only process data according to our instructions and to take sufficient security measures to protect such data. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Any violation of data or security laws by our third-party processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

When we transfer personal data out of the EU and EEA, we do so in compliance with the relevant data export requirements. After the European Court of Justice had declared the US Privacy Shield invalid in June 2020, there was uncertainty about how to comply with data protection requirements when transferring personal data from the EU to the US. Now, as the new model clauses from the European Commission and further guidance for the export of personal data are available, we have more clarity, however guidance from the authorities is developing continuously and needs to be monitored regularly to be able to ensure compliance. We are also subject to evolving European privacy laws on cookies and on e-marketing. The EU is in the process of replacing the e-Privacy Directive (2002/58/EC) with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each European member state. The draft e-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications, alters rules on third-party cookies, web beacons and similar technology and significantly increases fining powers to the greater of €20 million or 4% of total worldwide annual revenue. While the e-Privacy Regulation was originally intended to be adopted on May 25, 2018 (alongside the GDPR), it is still going through the European legislative process and it is still not clear when it will be adopted.

We process personal data in relation to participants in our clinical trials in the EEA, including the health and medical information of these participants. The GDPR is directly applicable in each EU Member State, however, it provides that EU Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose upon request to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm.

#### **Risks Relating to Employee Matters and Managing Growth**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the research and development, clinical and business development expertise of our managing directors and other key employees. We have entered into multi-year executive agreements with our managing directors. If any of our managing directors or other key employees becomes unavailable to perform services for us, we may not be able to find a qualified replacement in a timely fashion, which could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. We do not maintain any key man insurance for our managing directors at this time.

In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing managing directors and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We are moving certain of our research and certain other facilities from Heidelberg, Germany to Mannheim, Germany and may experience increased employee turnover as a result. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We will need to grow our organization, specifically to expand our development and regulatory capabilities, and we may experience difficulties in managing this growth, which could disrupt operations.***

We have 228 employees (219 full time equivalents), including those of our subsidiaries. As our development and commercialization plans and strategies develop, we expect to expand our employee base on an as-needed basis. Future growth would impose significant added responsibilities on management, including the need to identify, recruit, maintain, motivate and integrate additional employees. As part of our company's growth, we are moving our research and certain other facilities from Heidelberg, Germany to Mannheim, Germany, and we may experience disruption to our operations in connection with doing so. Our management may need to divert a disproportionate amount of their attention away from day-to-day activities and devote a substantial amount of time to managing these activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditure and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage future growth.

### **Risks Related to Our Common Shares**

***Our share price has been and may in the future be volatile, which could cause holders of our common shares to incur substantial losses.***

You should consider an investment in our common shares as risky and invest only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Our share price has been, and in the future may again be subject to substantial price volatility. In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common shares to fluctuate include:

- results and timing of our clinical studies and clinical studies of our competitors' products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and non-U.S. countries with respect to our product candidates or our competitors' products;
- failure to achieve pricing and/or reimbursement;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in estimates or recommendations by securities analysts who cover our securities;

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- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common shares;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises, including health epidemics and instability in the banking sector experienced in the first quarter of 2023;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- general market conditions and market conditions for biopharmaceutical stocks; and
- overall fluctuations in U.S. equity markets.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

***If our common shares are delisted from the Nasdaq, the liquidity of our common shares would be adversely affected and the market price of our common shares could decrease.***

Our common shares are currently listed on the Nasdaq and closed at \$0.75 on March 22, 2023. The Nasdaq has minimum requirements that a company must meet in order to remain listed on Nasdaq markets, including that we maintain a minimum closing bid price of \$1.00 per share for our common shares. If we fail to maintain such minimum requirements for a period of 30 consecutive business days, the Nasdaq will issue a notice that we are not in compliance and we will need to take corrective actions in order to not be delisted. There is no way to guarantee that any corrective measures we take would help us regain compliance with the minimum bid price requirement or maintain compliance with other Nasdaq listing rules. If Nasdaq were to make a final determination that our common shares must be delisted, the liquidity of our common shares would be adversely affected and the market price of our common shares could decrease. Our failure to be listed on Nasdaq or another national securities exchange would have a material adverse effect on the value of your investment in us.

***Future sales, or the possibility of future sales, of a substantial number of our common shares could adversely affect the price of the shares and dilute shareholders.***

Future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price of our common shares. We had approximately 149.3 million common shares outstanding as of March 15, 2023. If our existing shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through the issuance of equity securities in the future could be adversely affected. In addition, we have registered on a Form S-8 registration statement all common shares that we may issue under our equity compensation plans. As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We have a shelf registration statement pursuant to which we may offer and sell, in one or more offerings, our common shares, senior debt securities, subordinated debt securities, warrants, purchase contracts or units. We have also entered into a sales agreement to offer and sell our common shares under a prior registration statement pursuant to an “at-the-market” offering. Because the price per share of each share sold under the registration statement will depend on the market price of our shares at the time of the sale and other market conditions, it is not possible at this stage to predict the number of shares that ultimately may be offered and sold under the registration statement. If we sell common shares, convertible securities or other equity securities, existing shareholders may be diluted by such sales, and in certain cases new investors could gain rights superior to our existing shareholders. Any sales of our common shares, or the perception that such sales could occur, could have a negative impact on the trading price of our shares.

***We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.***

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Dutch laws and regulations with regard to such matters and intend to furnish quarterly financial information to the U.S. Securities and Exchange Commission, or SEC, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.



***As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.***

We are a foreign private issuer. As a result, in accordance with the listing requirements of The Nasdaq Global Market, or Nasdaq, we follow home country governance requirements and certain exemptions thereunder rather than comply with the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders in the United States. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires, inter alia, an issuer to have a compensation committee that consists entirely of independent directors, and Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. Also, Dutch law does not require that we disclose information regarding third party compensation of our directors or director nominees. As a result, our practice varies from the third-party compensation disclosure requirements of Nasdaq Listing Rule 5250(b)(3). In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

***We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.***

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. If, in the future, we are not a foreign private issuer, as of the end of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers, including the application of US GAAP, in the subsequent fiscal year. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our managing directors or supervisory directors may not be United States citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified supervisory directors.

***We are a Dutch public company with limited liability. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.***

We are a Dutch public company with limited liability (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our Articles of Association and by the laws governing companies incorporated in the Netherlands. However, there can be no assurance that Dutch law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

The rights of shareholders and the responsibilities of managing directors and supervisory directors may be different from the rights and obligations of shareholders and board members in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our management board and supervisory board are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

Our authorized share capital increased as of June 19, 2018, following an amendment of our Articles of Association approved by a resolution of the general meeting of shareholders. On August 4, 2020, following an amendment of our Articles of Association, approved by a resolution of the general meeting of shareholders, the composition of our authorized share capital was amended, and the cumulative preferred shares included in the share capital were abolished and converted into common shares. Our authorized share capital currently amounts to €3,119,500, comprised of 311,950,000 common shares, each with a nominal value of €0.01.

***Provisions of our Articles of Association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent or frustrate any attempt to replace or remove the then management board and supervisory board.***

Certain provisions of our Articles of Association may make it more difficult for a third party to acquire control of us or effect a change in our management board or supervisory board. These provisions include: staggered maximum four-year terms of our supervisory directors; a provision that our managing directors and supervisory directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our outstanding share capital (unless the removal was proposed by the supervisory board); and a requirement that certain matters, including an amendment of our Articles of Association, may only be brought to our shareholders for a vote upon a proposal by our management board that has been approved by our supervisory board.

***We are not obligated to and do not comply with all the best practice provisions of the Dutch Corporate Governance Code. This may affect your rights as a shareholder.***

As a Dutch company we are subject to the Dutch Corporate Governance Code, or DCGC. The DCGC contains both principles and best practice provisions that regulate relations between the management board, the supervisory board and the shareholders (*i.e.*, the general meeting of shareholders). The DCGC is based on a “comply or explain” principle. Accordingly, companies are required to disclose in their annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If they do not comply with those provisions (*e.g.*, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such non-compliance.

The DCGC applies to all Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with all the best practice provisions of the DCGC. In our annual report for the fiscal year ended December 31, 2022, we will report on our compliance with the DCGC. This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

***Claims of U.S. civil liabilities may not be enforceable against us.***

We are incorporated under the laws of the Netherlands, and our headquarters are located in Germany. Substantially all of our assets are located outside the United States. The majority of our managing directors and supervisory directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

The United States and the Netherlands currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the U.S. court. If and to the extent that the Dutch court finds that the jurisdiction of the U.S. court has been based on grounds which are internationally acceptable, that the proceedings before the U.S. court complied with principles of proper procedures, that recognition and/or enforcement of such judgment would not contravene the public policy of the Netherlands, and that recognition and/or enforcement of the judgment is not irreconcilable with a decision of a Dutch court rendered between the same parties or with an earlier decision of a foreign court rendered between the same parties in a dispute that is about the same subject matter and that is based on the same cause, provided that earlier judgment can be recognized in the Netherlands, the court of the Netherlands will, in principle, give binding effect to the judgment of the U.S. court. Dutch courts may deny the recognition and enforcement of punitive damages or other awards on the basis that recognition and enforcement would contravene public policy of the Netherlands. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. In addition, there is doubt as to whether a Dutch court would impose civil liability on us, our managing directors or supervisory directors or certain experts named herein in an original action predicated solely upon the U.S. federal securities laws brought in a court of competent jurisdiction in the Netherlands against us or such directors or experts, respectively. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Civil Procedure Code.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision not in line with German public policy principles. For example, recognition of court decisions based on class actions brought in the United States typically raises public policy concerns and judgments awarding punitive damages are generally not enforceable in Germany.

In addition, actions brought in a German court against us, our managing directors or supervisory directors, our senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our managing directors or supervisory directors, our senior management and the experts named in this Annual Report.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or managing directors or supervisory directors, officers or certain experts named herein who are residents of the Netherlands, Germany, or other countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement the required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also impair our ability to raise revenue, result in the loss of investor confidence in the reliability of our financial statements and subject us to regulatory scrutiny and sanctions, which in turn could harm the market value of our common shares.

We are required to disclose changes made in our internal controls and procedures and our management is required to assess the effectiveness of these controls annually. Our independent registered public accounting firm is required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***Changes in accounting standards could impact our results.***

The IASB, or other regulatory bodies, periodically introduce modifications to financial accounting and reporting standards or issue new financial accounting and reporting standards under which we prepare our consolidated financial statements. These changes can materially impact the means by which we report financial information, affecting our results of operations. Also, we could be required to apply new or revised standards retroactively.

***Although we do not believe we were a "passive foreign investment company" (a "PFIC") in 2022, we may be a PFIC in 2023 or one or more future taxable years. A U.S. investor may suffer adverse U.S. federal income tax consequences if we are a PFIC for any taxable year during which the U.S. investor holds common shares.***

Under the Internal Revenue Code of 1986, as amended, or the Code, we will be a PFIC for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets consist of assets that produce, or are held for the production of, "passive income." Passive income generally includes interest, dividends, rents, certain non-active royalties and capital gains. Although we have not performed a definitive PFIC analysis using U.S. federal income tax principles, based on certain estimates as to composition of our income and assets, including the implied value, based on our market capitalization, of our assets that produce non-passive income, during 2022, including, for this purpose, certain elements of our net working capital, we do not believe that we were a PFIC for our 2022 taxable year. However, there can be no assurance that the Internal Revenue Service, or the IRS, will agree with our conclusion. In addition, whether we will be a PFIC in 2023 or any future taxable year is uncertain because, among other things, we currently own a substantial amount of passive assets, including cash, and because the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time and the composition of our assets and income may vary substantially over time. The average quarterly value of our assets for purposes of determining our PFIC status for any taxable year (to the extent applicable) will generally be determined in part by reference to our market capitalization, which has fluctuated and may continue to fluctuate significantly over time. Accordingly, there can be no assurance that we will not be a PFIC for any future taxable year. In addition, we may, directly or indirectly, hold equity interests in other entities, including certain of our subsidiaries that are PFICs, or "Lower-tier PFICs."

If we are a PFIC for any taxable year during which a U.S. investor holds common shares, we generally will continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds common shares, even if we cease to meet the threshold requirements for PFIC status. Such a U.S. investor may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. To avoid the application of the foregoing rules, a U.S. investor can make an election to treat us and each Lower-tier PFIC as a qualified electing fund (a "QEF Election") in the first taxable year that we and each Lower-tier PFIC are treated as PFICs with respect to the U.S. investor. We currently intend to provide the information necessary for a U.S. investor to make a QEF Election with respect to us and each Lower-tier PFIC that we control for 2022 and for any future years with respect to which we determine that we or any Lower-tier PFIC that we control are or are likely to be a PFIC. A U.S. investor can also avoid certain of the adverse U.S. federal income tax consequences described above by making a mark-to-market election with respect to its common shares, provided that the common shares are "marketable." U.S. investors should consult their tax advisers regarding the availability and advisability of making a QEF Election or a mark-to-market election in their particular circumstances. See "Material U.S. Federal Income Tax Considerations" for further information regarding the consequences to a U.S. investor if we are a PFIC for any taxable year during which the U.S. investor holds common shares.

***One or more taxing authorities could challenge the German tax residency of the Company, and if such challenge were to be successful, the Company could be subject to increased and/or different taxes than we expect.***

By reason of the Company's incorporation under Dutch law, it is deemed tax resident in the Netherlands for purposes of the Dutch Dividend Withholding Tax Act 1965 and the Dutch Corporate Income Tax Act 1969. As long as it continues to have its place of effective management in Germany, and not in the Netherlands, under the Convention between the Federal Republic of Germany and the Netherlands for the avoidance of double taxation with respect to taxes on income of 2012 (the "German-Dutch tax treaty"), the Company should be considered to be exclusively tax resident in Germany. However, the applicable tax laws or interpretations thereof, including the German-Dutch tax treaty and the interpretation thereof, may change. Furthermore, whether the Company has its place of effective management in Germany and is as such tax resident in Germany is largely a question of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof and changes to applicable facts and circumstances (e.g., a change of board members or the place where board meetings take place), may result in the Company becoming a tax resident of a jurisdiction other than Germany, potentially resulting in the denial of benefits under the German-Dutch tax treaty. In that case, there would be a risk that both jurisdictions would levy dividend withholding tax, in addition to the risk of double taxation on the profits of the Company itself. These changes could have a material adverse impact on the Company's financial results and/or the future marketability of the Company's common shares.

#### **General Risk Factors**

***If any product liability lawsuits are successfully brought against us or any of our collaborators, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Despite mandatory product liability insurances in the countries in which we are conducting our clinical studies, we cannot exclude that any claims will be brought against us or our collaborators although product liability claims by participants enrolled in our clinical studies will be usually covered by our insurances. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for our future approved products;
- injury to our reputation;
- withdrawal of clinical study participants;

- termination of clinical study sites or entire trial programs;
- increased regulatory scrutiny;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

We have insurance, but our current insurance coverage and any additional coverage for further clinical studies may not be adequate to cover all liabilities that we may incur. We may need to increase and expand our insurance coverage when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

***Exchange rate fluctuations may materially affect our results of operations and financial condition.***

Potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period, such as the U.S. dollar. We have converted into euros only the portion of the proceeds from our financings and our research collaboration and license agreements with Genentech and Roivant that we expect will be spent in euros according to our budget. If the projected payments in either euro or U.S. dollar change, we may be subject to foreign exchange-rate risk. Currently, we do not have any other exchange rate hedging measures in place.



***Future acquisitions, strategic investments, partnerships or alliances could be difficult to integrate and/or identify, divert the attention of key management personnel, disrupt our business, dilute shareholder value and/or adversely affect our financial results.***

We may consider entering into partnerships or into acquisitions of other companies, businesses, assets or technologies that are complementary to our business and operations as part of our growth strategy. Acquisitions, partnerships, alliances and subsequent integrations thereof would require significant managerial, operational and financial resources and could result in a diversion of resources from our existing business, which in turn could have an adverse effect on our growth and business operations. We must necessarily base any assessment of potential acquisitions, partnerships or alliances on assumptions with respect to operations, profitability and other matters that may subsequently prove to be incorrect. Future acquisitions and alliances, as well as other investments, may not produce anticipated synergies or perform in accordance with our expectations. The cost and duration of integrating newly acquired businesses could also materially exceed our expectations. It is also possible that we may not identify suitable acquisition targets, strategic investments or partnership candidates. Our inability to identify such opportunities, or our inability to complete such transactions, may negatively affect our competitiveness and growth prospects. Any of these developments could have a material adverse effect on our business, financial condition and results of operations.

***We do not anticipate paying cash dividends, and accordingly, shareholders must rely on stock appreciation for any return on their investment.***

We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. As a result, capital appreciation, if any, of our common shares will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common shares.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.***

The trading market for our common shares depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

#### **ITEM 4. INFORMATION ON THE COMPANY**

##### **A. History and development of the company**

We are a clinical-stage immuno-oncology company focused on discovering and developing highly targeted cancer immunotherapies. Our product candidates represent an innovative approach to cancer treatment that seeks to harness the body's own immune defenses to fight tumor cells. The most potent cells of the human defense arsenal are types of white blood cells called innate immune cells (Natural Killer cells, or NK cells, and macrophages) and T cells. Leveraging our fit-for-purpose ROCK<sup>®</sup> platform, we develop proprietary, next-generation bispecific and trispecific antibodies, so-called innate cell engagers (ICE<sup>®</sup>), which are designed to direct innate immune cells and establish a bridge to cancer cells. Our innate cell engagers have the ability to bring innate immune cells into the proximity of tumor cells and trigger an activation cascade that leads to the destruction of cancer cells. Due to their novel tetravalent architecture with four binding domains, our innate cell engagers bind to their targets with high affinity. Different dosing schemes are being explored to allow for improved exposure in heavily pretreated patient populations. Based on their mechanism of action as well as the preclinical and clinical data we have generated to date, we believe that our product candidates as monotherapy and / or in combination, may ultimately improve response rates, clinical outcomes and survival in cancer patients, and could eventually become a cornerstone of modern targeted oncology care. Building on our leadership in the innate cell engager space, we are also developing novel antibody formats with the potential to tailor innate cell-engaging therapy to different indications and settings.

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Affimed was founded in 2000 based on technology developed by the group led by Professor Melvyn Little at Deutsches Krebsforschungszentrum (DKFZ), the German Cancer Research Center, in Heidelberg, Germany.

Focusing our efforts on antibodies that specifically bind to innate cells through CD16A, a key activating receptor, we have built a clinical and preclinical pipeline of innate cell-engaging bispecific antibodies designed to activate both innate and adaptive immunity. Compared to a variety of T cell-engaging technologies, our innate cell engagers appear to have a better safety profile and have the potential to achieve more potent and deeper immune responses potentially through enhancing crosstalk of innate and adaptive immunity. The safety profiles of our molecules make them suitable for development as combination therapies (e.g. with checkpoint inhibitors, or CPIs, adoptive NK cells or cytokines).

We are focusing our research and development efforts on three programs, for which we retain full global commercial rights, AFM13, AFM24 and AFM28. Because our tetravalent bispecific antibodies can be engineered to bind to different antigens that are known to be present on various cancer cells, our product candidates could be developed for the treatment of different cancer indications. We intend to clinically develop our product candidates to treat high medical need indications, including as a salvage therapy for patients who have relapsed after treatment with standard therapies, or patients who are refractory to these therapies, meaning they do not respond to treatment with standard therapies, whom we collectively refer to as relapsed/refractory patients. These patients have limited life expectancy and few therapeutic options. We believe this strategy will allow for a faster path to approval and will likely require smaller clinical studies compared to indications with more therapeutic options and larger patient populations. We believe such specialized market segments in oncology can be effectively targeted with a small and dedicated marketing and sales team. We currently intend to establish a commercial sales force in the United States and/or Europe to commercialize our product candidates when and if they are approved.

We also see an opportunity in the clinical development of our innate cell engagers in combination with other agents that harness the immune system to fight cancer cells, such as CPIs, adoptive NK cell transfer and cytokines. Such combinations of cancer immunotherapies may ultimately prove beneficial for larger patient populations in earlier stages of diseases, beyond the relapsed/refractory disease setting.

Our main offices and laboratories are located at the Technology Park adjacent to the German Cancer Research Center (DKFZ) in Heidelberg, where we employ 172 people, approximately 70% of whom have an advanced academic degree. Including Affimed Inc. and AbCheck (see description below) personnel, our total headcount is 228 (219 full-time equivalents). We are led by experienced executives with a track record of successful product development, approvals and launches, specifically in the area of biologics and biopharmaceuticals. Our supervisory board is made up of highly experienced experts from the pharmaceutical and biotech industries, including individuals with a background and expertise in hematological malignancies.

In 2009, we formed AbCheck s.r.o., our 100% owned, independently run antibody screening platform company, located in the Czech Republic. AbCheck discovers and optimizes human therapeutic antibodies with a versatile technology platform. Tailored to the specific needs of its customers and their desired target product profiles, AbCheck designs a personalized approach leveraging both cutting edge (e.g., microfluidics, rabbit mass humanization) and classical (e.g., phage/yeast display libraries) technologies to provide high quality leads. In addition to providing candidates for Affimed projects, AbCheck has multiple partnerships throughout the U.S. and Europe with globally active pharmaceutical and biotechnology companies such as Tusk Therapeutics, bluebird bio, Eli Lilly, Daiichi Sankyo, Pierre Fabre and others.

Our legal and commercial name is Affimed N.V. and we are a public company with limited liability (naamloze vennootschap) incorporated under Dutch law. Our principal executive offices are located at Technologiepark, Im Neuenheimer Feld 582, 69120 Heidelberg, Germany, and our telephone number is (+49) 6221-6743-60.

The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov). Our website can be found at [www.affimed.com](http://www.affimed.com). The information on our website is not incorporated by reference into this Annual Report, and you should not consider information contained on our website to be a part of this Annual Report.

## **B. Business overview**

### ***Our Strategy***

Our goal is to develop new treatment options for patients in need by activating innate immunity (e.g. NK cells and macrophages), the body's first line of defense, to fight cancer. We are developing single agent and combination therapies to treat a variety of cancers. Our novel proprietary antibody platform, ROCK<sup>®</sup>, delivers several unique types of next-generation tetravalent antibody formats, including bispecific and trispecific innate cell engagers. Based on the distinctive properties and mechanism of action of these products, which have demonstrated preclinical and / or clinical activity, we believe that our product candidates, alone or in combination, could eventually become a key element of improving clinical outcomes in cancer patients. Key elements of our strategy to achieve this goal are to:

- Rapidly advance the development of our clinical stage product candidates using a three-pronged development approach, including development (i) as monotherapy, (ii) in combination with adoptive NK cells, and (iii) in combinations with immunotherapies such as checkpoint inhibitors;
- Establish R&D and commercialization capabilities in Europe and in the United States;
- Use our technology platforms and intellectual property portfolio to continue to build our cancer immunotherapy pipeline;
- Maximize the value of our collaboration arrangements with Artiva, Genentech and Roivant, and establish new collaborations;
- Intensify our collaboration with academia; and
- Utilize AbCheck to generate and optimize antibodies.

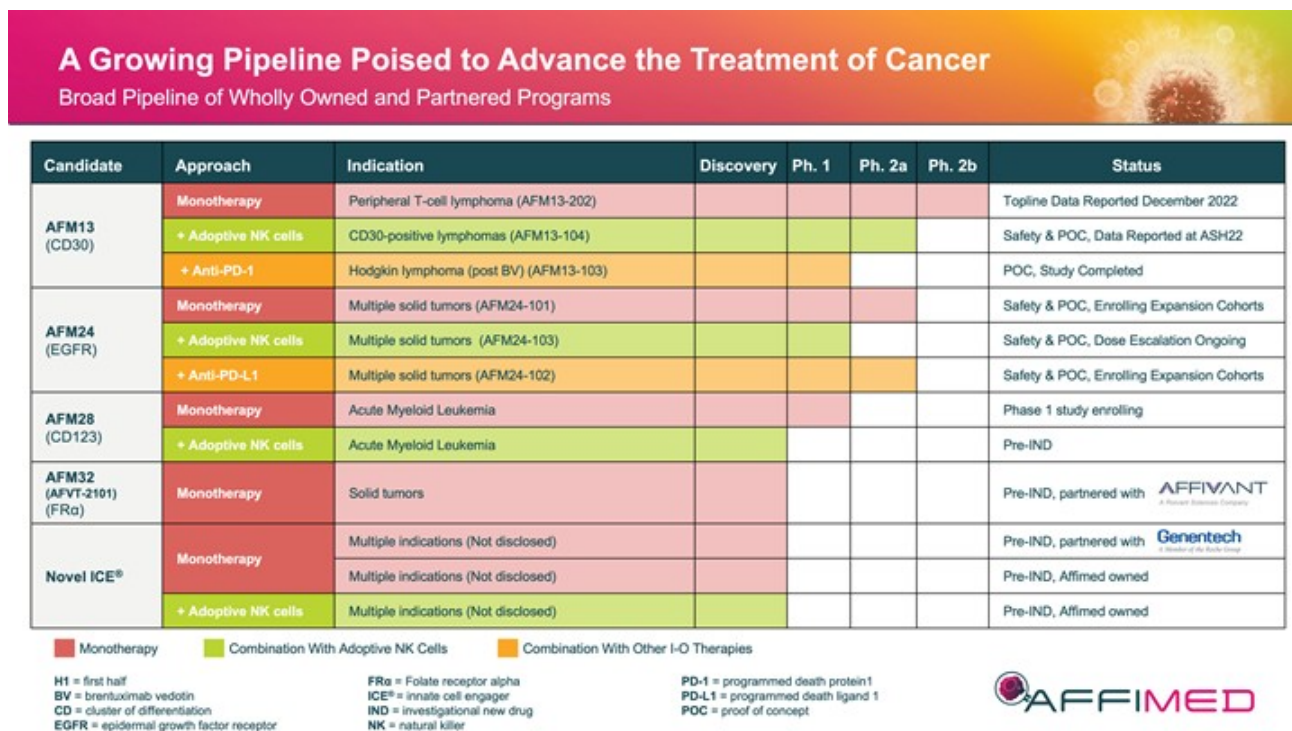
### ***Our Strengths***

We believe we are a leader in developing innate immunity-based cancer immunotherapies due to several factors:

- Our lead product candidate, AFM13, is a first-in-class innate cell engager for hematologic cancer indications;
- Our development candidate, AFM24, is a first-in-class innate cell engager for EGFR expressing solid tumor indications;
- Our development candidate, AFM28, is a first-in-class innate cell engager for AML;
- Our modular and versatile ROCK<sup>®</sup> platform, which we believe will enable future product candidates and collaborations with pharmaceutical companies;
- We retain global commercial rights for AFM13, AFM24 and AFM28;
- Our experienced management team has a strong track record in the development and commercialization of new medicines; and
- We have a strong technology base and solid patent portfolio in the field of targeted immuno-oncology.

## Our Research and Development Pipeline

We are developing a pipeline of innate cell engagers for the treatment of cancer as shown below:



Our most advanced candidate, AFM13, is a first-in-class ICE<sup>®</sup> designed for the treatment of certain CD30-positive (CD30+) malignancies, including Hodgkin lymphoma and certain non-Hodgkin lymphomas. AFM13 selectively binds to CD30, a clinically validated target, and CD16A, an integral membrane glycoprotein receptor expressed on the surface of NK cells and macrophages, triggering a signal cascade that leads to the destruction of CD30-positive tumor cells. In contrast to conventional full-length antibodies, AFM13 does not bind to CD16B, which prevents binding to other cell types, e.g., neutrophils, and binds with equal affinity to CD16A polymorphisms at position 158. Furthermore, AFM13 binds CD16A with an approximately 1000-fold higher affinity than monoclonal antibodies thereby significantly increasing potency and efficacy as preclinically demonstrated. AFM13 was investigated as monotherapy in a phase 2 study (REDIRECT) in patients with relapsed/refractory peripheral T-cell lymphoma (PTCL), and is being investigated in combination with adoptive NK cells in a Phase 1/2a clinical study in collaboration with the MD Anderson Cancer Center in patients with CD30+ lymphomas. Topline data from the REDIRECT study were reported in December 2022, and the Company expects to present comprehensive data from the study at a scientific conference in 2023. In November 2022, we announced a collaboration with Artiva Biotherapeutics with the goal of advancing the development of the combination of AFM13 with Artiva's AB-101 NK cell therapy into a potential registration enabling study. We expect to submit an IND for the combination of AFM13 with AB-101 in the first half of 2023 and, subject to FDA clearance of the IND, to initiate a clinical study during 2023.

Our second candidate, AFM24, is a tetravalent, bispecific epidermal growth factor receptor (EGFR) and CD16A-binding innate cell engager. AFM24 is designed to address limitations, such as toxicities or treatment resistance, associated with current therapeutic anti-EGFR monoclonal antibodies, while also offering the potential for better efficacy and safety by using activation of innate immunity to target EGFR-expressing solid tumors rather than inhibition of EGFR-mediated signal transduction. AFM24 is currently being investigated as monotherapy in a first-in-human phase 1/2a study, and in two combination clinical studies investigating AFM24 with adoptive NK cells and a PD-L1 inhibitor.

Our third, wholly-owned ICE<sup>®</sup> molecule, AFM28, was developed from our ROCK<sup>®</sup> platform and is designed to bind to CD123, an established target in myeloid malignancies. We chose CD123 as it is almost universally expressed on leukemic blasts and leukemic stem cells in patients with AML, both at diagnosis and at relapse, and independently of cytogenetic risk. AFM28 is being developed for the treatment of patients with acute myeloid leukemia. We believe that AFM28 could be the key to novel treatment approaches that can fulfill several unmet needs. We advanced AFM28 into preclinical studies in 2020 and initiated recruitment for a first-in-human phase 1 study in the first quarter of 2023.

In August 2018, we entered into a research collaboration and license agreement with Genentech, a member of the Roche Group, for the development and commercialization of a number of product candidates based on our novel NK cell engager-based immuno-therapeutics to treat multiple cancers. The agreement included a license to AFM26, a tetravalent, bispecific B cell maturation antigen (BCMA)- and CD16A-binding ICE<sup>®</sup> from our fit-for-purpose ROCK<sup>®</sup> platform, for the treatment of multiple myeloma. AFM26 is now known as RO7297089. RO7297089 employs a unique mechanism of action through high affinity engagement of NK cells and has demonstrated in vitro efficacy against cells with very low levels of BCMA expression. NK cell binding of RO7297089 is largely unaffected by IgG competition. During 2020, Genentech initiated a phase 1 study for RO7297089. Treatment with RO7297089 was well-tolerated at the dose levels tested, although infusion reactions necessitated long infusion duration for the first dose. Activity has been observed to date with partial responses at doses up to 1080 mg. There were no DLTs and a recommended phase 2 dose has not been identified. Genentech has decided not to progress with clinical development of RO7297089. The decision to discontinue the phase 1 study does not impact the development of other targets pursuant to the collaboration agreement with Genentech. Affimed is continuing its work with Genentech and during 2022 handed over a number of additional product candidates for further investigation by Genentech.

AFVT-2101 (formerly AFM32), another ICE<sup>®</sup> candidate in preclinical development against folate receptor alpha, is being investigated under a License and Strategic Collaboration with Roivant Sciences Ltd. ("Roivant"), pursuant to which we granted Roivant a license to develop and commercialize AFVT-2101 and options to license additional novel ICE<sup>®</sup> molecules against other targets. Roivant has announced its intention to submit an IND for AFVT-2101 in the first half of 2023.

We believe that our collaborations help to validate and more rapidly advance our discovery efforts, technology platforms and product candidates. As part of our business development strategy, we aim to enter into additional research collaborations in order to derive further value from our platform and more fully leverage its potential.

#### **COVID-19**

In response to the COVID-19 pandemic, we have implemented mitigation procedures to ensure the safety of trial participants and healthcare professionals and that drug supply and other trial-related materials are ready and available for patients enrolled in our clinical trials. We are closely monitoring and adhering to relevant federal and local guidelines on COVID-19 to ensure the safety and health of our global workforce and help limit the spread of COVID-19, while maintaining business continuity. We will continue to work closely with clinical sites as well as respective competent authorities to ensure the safety of trial participants and healthcare professionals, as well as the appropriate use of healthcare resources during the COVID-19 pandemic, while preserving the conduct and data integrity of our clinical studies. For example, in January 2022, we announced that we would no longer pursue the TMF cohort in our phase 2 clinical trial evaluating AFM13 as monotherapy due to continuing challenges enrolling patients as a result of the COVID-19 pandemic.

At this time, our contract manufacturers are operating without interruption, and there is sufficient material for our ongoing clinical studies. We are continually assessing the potential impact of the COVID-19 pandemic on patient enrollment and site activation in our clinical studies, and we will update trial timelines to the extent that changes arise as a result of the COVID-19 pandemic.

## **Immune System and Cancer Background**

### ***Immune System***

The human immune system is characterized by an early, nonspecific initial response called innate immunity, and a highly specific response adapted to pathogenic or tumorigenic antigens called adaptive immunity. Although the human immune system is normally capable of recognizing foreign or aberrant cells, cancer cells have developed highly effective ways to escape the surveillance and defense mechanisms of the immune system. As a result, immune cells such as NK cells and macrophages (parts of the innate immune system) and T cells (a part of the adaptive immune system) cannot recognize tumor cells as foreign or aberrant and therefore cannot fight them.

- **NK cells:** NK cells are important mediators of the innate immune system and can display cytotoxic, or cell-killing, activity against “altered self” (virus-infected and cancerous) cells. They were named “natural killers” because they recognize altered structures without the need for antigen processing and presentation. NK cells possess a large number of receptors that activate NK cells to destroy deviant cells.
- **Macrophages:** Macrophages are mature monocytes that are present in all tissues and patrol the body in order to engulf and digest microorganisms, dead cells or cellular debris in a process called phagocytosis. In this role they are an important first line of defense of innate immunity and very important for inducing inflammation, secreting signaling molecules and presenting antigens to adaptive immune cells, all being important for the induction of immune responses.
- **T cells:** T cells are part of the adaptive immune system and only target cells that present an antigen on their surface which has been presented before to the T cells by so-called antigen-presenting cells, such as dendritic cells and macrophages. The antigen presentation triggers a biological cascade, resulting in the clonal expansion of antigen-specific T cells.

Better understanding of the fundamentals of cellular and molecular tumor immunology has identified many ways by which the immune system can be augmented to treat cancer, including priming/boosting of the immune system, T cell modulation, reducing immunosuppression in the tumor microenvironment and enhancing adaptive immunity. This new area of medicine, termed cancer immunotherapy, has the potential to offer adaptable and durable cancer control across a variety of tumor types. Our ROCK<sup>®</sup> platform-based immune cell engagers enable a direct interaction of NK cells, macrophages or T cells with cancer cells, leading to the destruction of the tumor cells.

### ***Cancer***

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion, forming malignancies that can invade other parts of the body. In normal tissues, the rates of new cell growth and cell death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of gene mutations, causing unregulated cell growth that leads to tumor formation. While tumors can grow slowly or rapidly, the dividing cells will nevertheless accumulate, and the normal organization of the tissue will become disrupted. Cancers subsequently can spread throughout the body by processes known as invasion and metastasis. Cancer cells that arise in the lymphatic system and bone marrow are referred to as hematological malignancies. Cancer cells that arise in other tissues or organs are referred to as solid tumors.

According to the American Cancer Society, cancer is the second most common cause of death in the United States. In the United States, more than 1.9 million new cases of cancer are expected to be diagnosed in 2023, and more than 600,000 deaths from cancer are expected to occur. The 5-year relative survival rate for all cancers diagnosed during 2012-2018 was 68%. According to a United States National Institutes of Health National Cancer Institute estimate, national expenditures for cancer care in the United States in 2018 were approximately \$151 billion.



The most common methods of treating patients with cancer are surgery, radiation and drug therapy. For patients with localized disease, surgery and radiation therapy are particularly effective. Drug therapies are generally used by physicians in patients who have cancer that has spread beyond the primary site or cannot otherwise be treated through surgery, such as most hematological malignancies. The goal of drug therapies is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the proliferation, growth and survival of cancer cells. In many cases, drug therapy entails the administration of several different drugs in combination. Over the past several decades, drug therapy has evolved from non-specific drugs that kill both healthy and cancerous cells, to drugs that target specific molecular pathways involved in cancer.

An early approach to pharmacological cancer treatment was to develop drugs, referred to as chemotherapies or cytotoxic drugs, which kill rapidly proliferating cancer cells through mechanisms, such as stopping cell division, disrupting cell metabolism or causing damage to cellular components required for tumor survival and rapid growth. While these drugs have been effective in the treatment of some cancers, cytotoxic drug therapies act in an indiscriminate manner, killing healthy cells along with cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a narrow therapeutic window, i.e., dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

The next approach to pharmacological cancer treatment was to develop drugs, referred to as targeted therapeutics, including monoclonal antibodies, which are antibodies that derive from a single parent cell, that target specific biological molecules in the human body that play a role in cell growth and the spread of cancer. Included in this category are small molecule drugs as well as large molecule drugs, also known as biologics. With heightened vigilance and new diagnostic tests, targeted therapies (including monoclonal antibodies such as Herceptin<sup>®</sup>, Rituxan<sup>®</sup>, Erbitux<sup>®</sup> and Avastin<sup>®</sup> as well as small molecules such as Nexavar<sup>®</sup> and Tarceva<sup>®</sup>), have resulted in improvements in overall survival for many cancer patients. More recently, antibodies have been developed that are optimized regarding their effector function, also known as Fc optimized antibody drugs, for example obinutuzumab. These molecules are designed to engage NK cells and macrophages more effectively in the elimination of cancer cells.

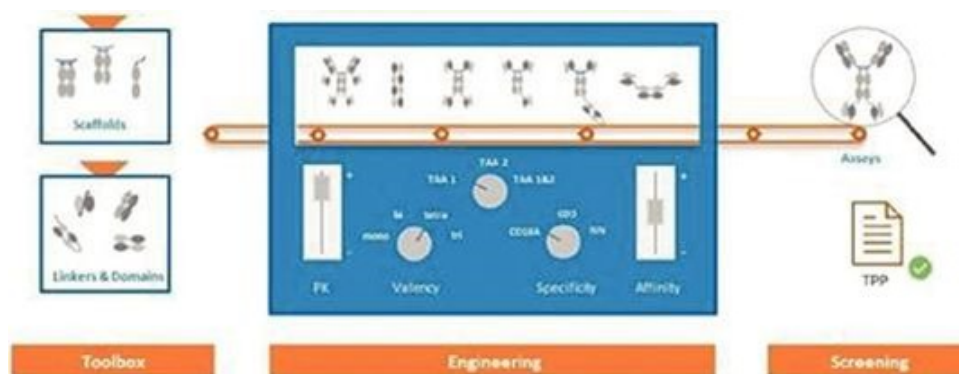
Cancer immunotherapy plays an increasingly important role among emerging cancer drug therapies. The science behind immunotherapies is to harness the body's own immune system to fight tumor cells. There are different approaches: vaccinations, checkpoint modulators, T cell and innate cell engagers. For example, bispecific antibodies, or cellular therapies transform a patient's own T cells to express specific chimeric antigen receptors (CARs). Ipilimumab (Yervoy<sup>®</sup>), sipuleucel-T (Provenge<sup>®</sup>), and more recently nivolumab (Opdivo<sup>®</sup>), pembrolizumab (Keytruda<sup>®</sup>), and blinatumomab (Blincyto<sup>®</sup>) were amongst the first cancer immunotherapies to enter the market. Our platforms of bi- antibodies add further promise to the field of immuno-oncology.

## **Our Technologies**

We have developed our proprietary fit-for-purpose ROCK<sup>®</sup> antibody platform to enable the generation of first-in-class multivalent, multi-specific immune cell engagers. Our antibodies have been shown to retarget innate and adaptive immune cells. ROCK<sup>®</sup> enables us to tailor tetravalent, bispecific immune cell engagers with high affinity and avidity, as well as variable pharmacokinetic (PK) profiles for different indications and settings. Leveraging this platform, we are able to generate molecules against validated oncology targets to address the limitations of existing standard treatments.



## Schematic Representation of our Fit-For-Purpose ROCK Platform



Our ROCK® platform offers modularity and versatility for customizable antibody generation, is differentiated from other technologies and is designed to deliver immune cell engagers that:

- target different tumor-associated antigens;
- enable tumor cell killing even with low target expression;
- demonstrate high affinity binding and avidity based on bivalency;
- recruit innate immune cells through anti-CD16A-specific epitopes;
- offer different PK profiles;
- possess long cell retention time; and
- show evidence of specific innate immune cell activation and their tumor infiltration (CD16A engagers).

Leveraging our fit-for-purpose ROCK® platform, we develop proprietary, next-generation bispecific antibodies, so-called innate cell engagers (ICE®). These ICE® molecules are designed to direct and establish a bridge between innate immune cells and cancer cells. Our innate cell engagers have the ability to create an immunological synapse between innate immune cells and cancer cells and trigger an activation cascade that leads to the destruction of cancer cells. Due to their novel tetravalent architecture (which provides for four binding domains), our innate cell engagers bind to their targets with high affinity and have half-lives that support intravenous administration and dosing schedules similar to monoclonal antibodies (mAbs) to achieve potent antitumor efficacy. In addition to our lead candidates, AFM13, AFM24 and AFM28, we are developing a variety of tetravalent, bispecific antibody formats with the potential to tailor immune-engaging therapies to different indications and settings.

### ***Innate Cell Engagers***

Our fit-for-purpose ROCK® platform enables the design and development of various antibody formats.

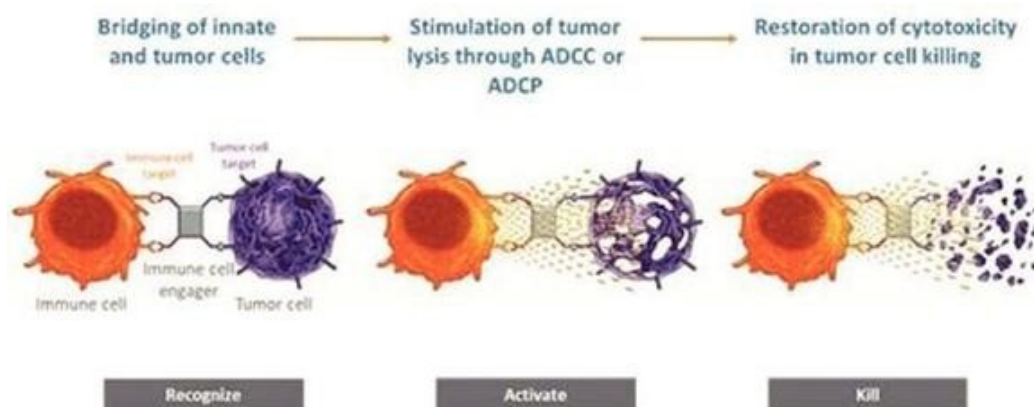
Specifically, our innate cell engagers are designed to have the following properties:

- bispecific or trispecific targeting;
- binding with high specificity, or selectivity;

- binding with high affinity/avidity, or strength;
- molecular weight allowing for intravenous bolus administration; and
- stable structure conducive to efficient and cost-effective manufacturing.

Innate cell engagers bind to innate immune cells and enable both the recognition of tumor cells and their redirection to these tumor cells by forming an immunological synapse. These cells then release perforins, creating pores in the tumor cell membrane through which granzymes enter the cell, triggering apoptosis and resulting in tumor cell death.

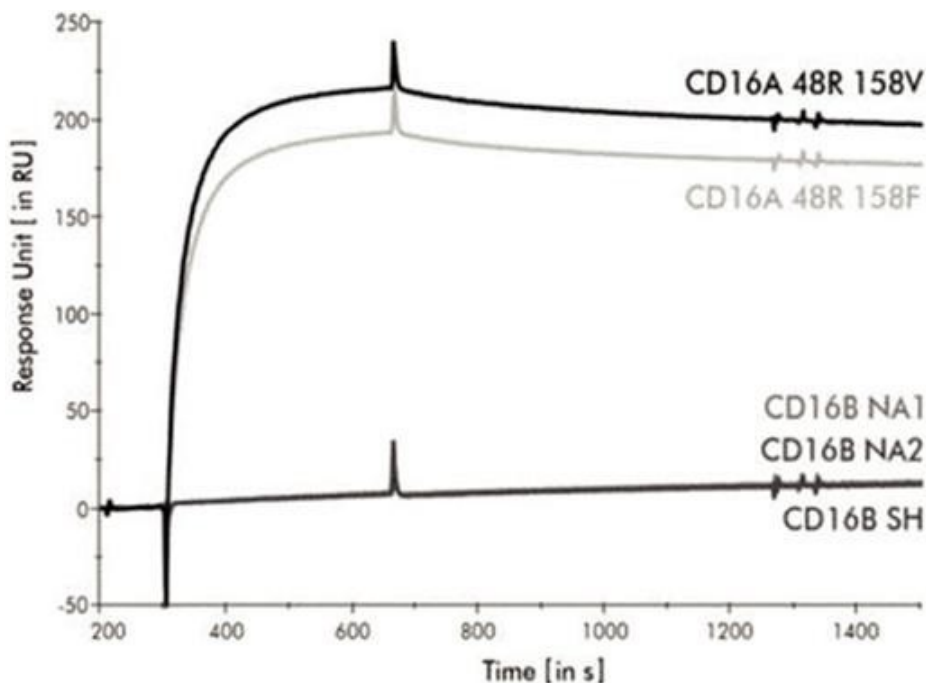
**Schematic representation of the mode of action of a tetravalent bispecific innate cell engager**



Innate immune cells, such as NK cells and macrophages, distinguish between healthy cells and foreign or aberrant cells through a process that is governed by a complex interaction of activating and inhibitory receptors that regulate their activity. While innate immune cells can bind to the Fc regions of native full-length antibodies through Fcγ receptors to induce a cytotoxic effect, our ICE<sup>®</sup> molecules are designed to enhance the activity of innate immune cells in killing targeted tumor cells because they bind the FcγRIIIA (CD16A) receptor on innate immune cells with high specificity and approximately 1,000-fold higher affinity than IgG-based antibodies, and greater than 25-fold higher affinity than typical Fc-optimized IgG antibodies.

CD16A is an integral membrane glycoprotein found on the surface of innate immune cells, namely NK cells and macrophages but not neutrophils. Classical mAbs bind not only to CD16A, but, to our knowledge, also to the highly homologous CD16B, an isoform differing from CD16A by only a few amino acids. CD16B is expressed on neutrophils, which are the most numerous white blood cells (leukocytes), and blood plasma contains high levels of soluble CD16B cleaved from the daily turnover of apoptotic neutrophils. Thus CD16B, being readily available to bind to any Fc-based antibody formats, facilitates target-mediated drug disposition for such antibodies. To engage and activate innate immune cells, we have generated a highly effective and specific human antibody that specifically targets the CD16A receptor and does not cross-react with CD16B. This antibody also binds to both CD16A allotypes (amino acid 158 with either valine or phenylalanine) with equal affinity, a polymorphism that has been shown to reduce efficacy of marketed classical antibodies such as trastuzumab or elotuzumab (see figure below).

**Binding of Innate Cell Engager to CD16A (high-and low affinity genetic variants (allotypes) 158V and 158F, respectively) and to CD16B (SH, NA1 and NA2 allotypes), the latter showing no response (i.e. no binding)**



Our lead innate cell engager AFM13, binds to CD16A on innate immune cells and to CD30, a receptor found on malignant cells that have been implicated in lymphoma, including Hodgkin Lymphoma (HL) and T cell lymphoma.

#### CD30-positive Malignancies

CD30 is a cell membrane protein and tumor marker of different hematological malignancies, including PTCL, CTCL, HL and DLBCL.

Hodgkin Lymphoma is a type of lymphoma, a cancer originating from white blood cells called lymphocytes. There are approximately 9,000 new cases of HL in the United States every year and about 20,000 new cases in North America, the European Union and Japan. Depending on disease stage, patients with newly diagnosed HL are treated primarily with chemotherapy and sometimes in combination with radiotherapy. The current initial standard regimens are highly effective, but associated with acute and chronic toxicity. A number of patients are either refractory to or relapsing from standard therapy that included chemotherapy followed by Adcetris<sup>®</sup>, and we believe these represent a total of approximately 4,000-5,000 patients every year in North America, the European Union and Japan.

Adcetris<sup>®</sup> is the first approved targeted therapy for HL patients that are relapsed/refractory to second line treatments. Adcetris<sup>®</sup> targets CD30, the same target as AFM13, but has a different mode of action, acting as a targeted chemotherapy, rather than as a targeted immunotherapy. As an antibody-drug conjugate, Adcetris<sup>®</sup> delivers a toxin (monomethyl auristatin E) to the cells that carry the CD30 antigen. The drug conjugate is internalized by the tumor cell, which is then destroyed. In a phase 2 clinical study, Adcetris<sup>®</sup> treatment in relapsed/ refractory HL patients resulted in an overall response rate of 75% and a complete response rate of 33%. However, the median progression free survival after Adcetris<sup>®</sup> is 5.6 months. In addition, the treatment is associated with considerable adverse events like neutropenia (low neutrophils) and neuropathy (damage to the peripheral nervous system).

The FDA and EMA have approved nivolumab in classical HL patients that have relapsed or progressed after autologous hematopoietic stem cell transplantation and Adcetris<sup>®</sup> in 2016. In 2017, the FDA granted accelerated approval, and the European Commission granted approval for pembrolizumab in adult and pediatric patients with refractory cHL who have relapsed after 3 or more prior lines of therapy, and the European Commission granted approval for pembrolizumab in adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin. In 2020, the FDA approved an expanded label for pembrolizumab in relapsed or refractory cHL. Overall response rates for the anti-PD-1 antibodies (nivolumab and pembrolizumab) in relapsed/refractory classical HL patients post brentuximab vedotin are 66 to 69%, with complete remission rates of 14-25%.

Beyond HL, other CD30+ hematological malignancies include T cell lymphoma, or TCL, and diffuse large B cell lymphoma, or DLBCL.

Approximately 4% of all new cancer cases in the US are NHL (SEER Database). In 2022, approximately 80,000 new cases of NHL were diagnosed in the US (SEER estimate). 5-10% of all Non-Hodgkin Lymphomas (NHL) are peripheral T-Cell Lymphomas (PTCL) and the majority are B-Cell Lymphomas, with approximately a third of NHL being DLBCL. There are between 4,000-8,000 newly diagnosed cases of PTCL in the US every year, of which approximately 50-60% are positive for CD30. There are approximately 27,000 newly diagnosed DLBCL patients in the US every year, of which approximately one fifth to one third are CD30+. Together, TCL and DLBCL contribute approximately 7,000-9,000 relapsed/refractory CD30+ cancer cases per year in North America, the European Union and Japan.

### ***EGFR-positive Malignancies***

Current treatment options for solid tumors consist of a mix of surgery, chemotherapy, radiotherapy and targeted therapies. While chemotherapy or radiotherapy were historically standard treatment strategies, specific tumor characteristics currently guide decision-making for an optimal treatment regimen for individual patients. This has led to the implementation of innovative treatments as standard of care in many solid tumors, including monoclonal antibodies and tyrosine kinase inhibitors.

EGFR, an important target that is exploited by these targeted therapies, is expressed in a wide range of solid tumors and is considered a validated target for their treatment. Erbitux<sup>®</sup> and Vectibix<sup>®</sup> are anti-EGFR monoclonal antibodies that are approved for the treatment of RAS-wild type metastatic colorectal cancer (CRC), which represents a subset of ~45-50% of all CRC patients. However, Erbitux<sup>®</sup> and Vectibix<sup>®</sup> are not effective in KRAS mutated CRC. The activating KRAS mutations put RAS in a constitutively activated status that bypasses the signal transduction inhibition produced by EGFR targeting antibodies. In addition, Erbitux<sup>®</sup> is also approved for the treatment of locally advanced and recurrent/metastatic head and neck cancer (HNSCC). The anti-EGFR mAb Necitumumab is approved for squamous cell carcinoma of the lung.

Beyond these approved indications, there are signals of clinical activity of anti-EGFR mAbs from early clinical studies in a wide range of different indications.

Immunotherapies play an increasing role in solid tumors. PD-1 checkpoint inhibitors have been approved for the treatment of many different types of cancer, including melanoma, lung cancer, renal cancer, gastric / gastroesophageal cancer, bladder cancer and head and neck cancer. Many studies with cancer immunotherapies are ongoing. It is expected that immunotherapies will play an increasing role in the standard treatment of solid tumors. However, even with these advances, cure is still the exception for the majority of late-stage tumors, in particular metastatic tumors, and the medical need for new and safe treatment approaches remains generally high for solid tumors.

## **Our Product Candidates**

Our development pipeline currently comprises three distinct product candidates for which we retain full commercial rights: AFM13, AFM24 and AFM28 . Initially, we intend to pursue indications in which the medical need is high and for which there is a significant population of patients needing treatment in the salvage setting. This unmet medical need could mean that our therapeutics could be approved on an expedited basis. If and when we obtain approval for our product candidates as salvage therapies, we plan to explore whether they could also be used as first- or second-line treatments, most likely in combination with one or more treatments that comprise the existing standard of care. All of our product candidates have the potential to target several indications, which could represent significant additional commercial opportunities in the future.

### **AFM13**

#### **Overview**

AFM13 is a first-in-class innate cell engager that is engineered to bind with high affinity to both CD30-expressing tumor cells and to CD16A surface proteins to activate NK cells and macrophages. AFM13 is intravenously administered and has several advantageous characteristics:

- By targeting CD16A, AFM13 binds to NK cells and macrophages but not to neutrophils and is therefore more selective than full-length antibodies that bind to both CD16A and CD16B.
- Preclinical experiments have demonstrated that the cytotoxic potency of AFM13 is consistently higher than native and Fc-enhanced anti-CD30 full-length antibodies.
- AFM13 has the potential to be effective for all known and relevant genetic variants of CD16A.

The clinical and preclinical data that we have generated to date suggest that AFM13 appears to be well-differentiated from Adcetris<sup>®</sup>, an approved targeted therapy for HL and TCL patients. Although AFM13 employs the same target as Adcetris<sup>®</sup>, namely CD30, the two compounds are fundamentally different in their mechanism of action. Adcetris<sup>®</sup> is a targeted chemotherapy, while AFM13 is a targeted immunotherapy. Adcetris<sup>®</sup> delivers a toxin (monomethyl auristatin E) to the cells that carry the CD30 receptor, and the cell is killed by the action of the toxin after its internalization and release from the antibody. In contrast, AFM13 does not need to enter the cell, but serves as a connector on the cell surface between the CD30 receptor and a CD16A-positive immune cell. Once the cells are in contact, the killing activity of the immune cell is triggered.

Tumor cells have the ability to activate a multi-drug resistance system, or MDR, which we believe may contribute to the development of resistance to Adcetris<sup>®</sup>. The MDR, however, does not affect the efficacy of an immunotherapy like AFM13. We believe that this difference may not only translate into efficacy of AFM13 in patients relapsing from Adcetris<sup>®</sup> therapy, but ultimately into a longer clinical benefit. In addition, the off-target toxicity of Adcetris<sup>®</sup> toxin monomethyl auristatin E causes severe neutropenia (low neutrophils) and neuropathy (damage to the peripheral nervous system). We believe AFM13 may avoid these side effects because it does not introduce a toxin such as monomethyl auristatin E into the cells. Hence, AFM13 may address Adcetris<sup>®</sup> safety limitation.

AFM13 has been granted orphan drug status for the treatment of HL in the United States and the European Union, and for T-cell lymphoma in the United States.

### ***Clinical development of AFM13 as monotherapy in T-cell Lymphoma***

In November 2019, the first patient was dosed in a phase 2 registration-directed study of AFM13 as monotherapy in relapsed or refractory patients with CD30-positive peripheral T cell lymphoma (PTCL). In January 2022, we announced that we had completed enrollment of patients with PTCL in the registration-relevant portion of the study. Topline results from the study were reported in December 2022. In 108 patients enrolled with relapsed / refractory PTCL, a 32.4% objective response rate and 10.2% complete response rate was observed. The safety profile of AFM13 was well managed and consistent with previously reported data of prior and ongoing clinical studies with AFM13. Median duration of response (DoR) was 2.3 months, median progression-free survival was 3.5 months and median overall survival was 13.8 months.

Based on the compelling data seen in Hodgkin lymphoma for the combination of AFM13 with cord blood-derived NK cells in the AFM13-104 study – as described in the section “Clinical development of AFM13 in combination with adoptive NK cells” - we believe that the combination with AB-101 has a higher probability to deliver increased anti-tumor activity and a more durable clinical benefit to address the unmet need in the PTCL patient population. Accordingly, we do not intend to pursue an accelerated approval for AFM13 monotherapy in PTCL and will focus investment on clinical development in the combination of AFM13 with Artiva’s AB-101 NK cell product.

We have also supported a phase 1b/2a IST of AFM13 in patients with relapsed or refractory CD30-positive lymphoma with cutaneous presentation led by investigators at Columbia University in New York. In addition to determining clinical efficacy, this study was also translational in nature, designed to allow for serial biopsies that enable assessment of NK cell biology and tumor cell killing within the tumor microenvironment. Final clinical efficacy and safety analysis of this study was presented at the annual ASH conference in December 2020. In 15 patients (dosed at 1.5-7.0 mg/kg) AFM13 was well-tolerated and showed therapeutic activity as a single agent, with an ORR of 42% (6 of 14 patients, 1 patient not assessed). In detail, one complete response (CR), five partial responses (PRs) and five stable diseases (SDs) were observed. An analysis of biomarker correlatives showed a decrease in circulating NK cells (CD56+ CD3- , CD56+ CD16+, NKp46+) during therapy, with post-therapy recovery. In addition, increased CD69 expression on circulating NK cells from responders vs. non-responders was demonstrated. Tumor biopsies showed increased infiltration of CD56+ NK cells pre-therapy in responders compared to non-responders, while circulating CD4+ CD25+ T cells (Tregs) decreased in responders compared to non-responders.

### ***Clinical development of AFM13 in combination with adoptive NK cells***

In December 2016, we entered into a clinical development and commercialization collaboration with The MD Anderson Cancer Center (MDACC) to evaluate AFM13 in combination with MDACC’s cord-blood derived NK cell product. MDACC conducted preclinical research aimed at investigating its NK cells derived from umbilical cord blood in combination with AFM13. In December 2018, we presented data at the ASH Annual Meeting, outlining the successful approach of a novel premixed product comprising expanded cord-blood derived NK cells loaded with AFM13 to redirect their specificity against CD30-positive malignancies.

In September 2020, MDACC dosed the first patient in a phase 1/2 study. The study is designed to administer a stable complex of AFM13 pre-complexed with cord blood-derived allogeneic NK cells in different doses (numbers of pre-complexed NK cells) to patients with relapsed/refractory CD30-positive lymphoid malignancies followed by three doses of AFM13 as monotherapy. We fund research and development expenses for this collaboration and have licensed exclusive worldwide rights to further develop and commercialize any product developed under the collaboration. As of December 2022, a total of 41 patients with CD30-positive relapsed or refractory Hodgkin and non-Hodgkin lymphomas (36 and 5 patients, respectively) were treated with the novel combination of cbNK cells pre-complexed with AFM13. Three patients were treated with  $1 \times 10^6$ , three patients with  $1 \times 10^7$  and 35 patients with  $1 \times 10^8$  AFM13-pre-complexed cbNK cells per kg body weight. Of the 35 patients treated at  $1 \times 10^8$  per kg dose level, 31 patients had Hodgkin lymphoma and 4 patients had non-Hodgkin lymphoma.



As of the cutoff date, 38 of 41 patients (93%) had achieved an objective response to the treatment according to investigator assessment, with 27 complete responses (CR) and 11 partial responses (PR). In the 31 patients with Hodgkin Lymphoma treated at the recommended phase 2 dose (RP2D) level of  $10^8$  cbNK cells per kg, a 97% ORR and 77% CR rate was observed according to investigator assessment. In four patients with non-Hodgkin Lymphoma treated at the RP2D, three patients achieved an objective response with one patient achieving a complete response according to investigator assessment. Of note, there were no instances of serious adverse events such as cytokine release syndrome, immune cell-associated neurotoxicity syndrome or graft-versus-host disease.

In November 2022, we announced a collaboration with Artiva Biotherapeutics with the goal of advancing the development of the combination of AFM13 with Artiva's AB-101 NK cell therapy into a potential registration enabling study. We expect to submit an IND for the combination of AFM13 with AB-101 in the first half of 2023 and, subject to FDA clearance of the IND, to initiate a clinical study during 2023.

We published preclinical data with the German Cancer Research Center (DKFZ) presenting evidence of AFM13 modulating NK cells by sensitizing them to IL-2 and/or IL-15 stimulation. In this study, after exposure to AFM13, the NK cells showed improved IL-2- and IL-15-mediated proliferation and cytotoxicity. This data supports the rationale for further investigation of combining our NK cell engagers with IL-2-or IL-15 to potentially achieve deeper clinical responses.

### ***Clinical development of AFM13 in combination with checkpoint inhibitors***

In 2019, we completed a phase 1b clinical study investigating the combination of AFM13 with Merck's anti-PD-1 antibody Keytruda® (pembrolizumab) in HL patients who had relapsed after or were refractory to chemotherapy and Adcetris®. The study was designed to establish a dosing regimen for the combination therapy and to assess its safety and efficacy. In this study, the combination was well-tolerated with most of the adverse events observed to be manageable with standard care and mild to moderate in nature. Best response assessment data from 24 patients treated at the highest AFM13 dose level (7 mg/kg) as reported by central read, showed an objective response rate (ORR) of 88% (21 of 24 patients), including complete metabolic responses (CmR) in 46% (11 of 24 patients) and partial metabolic responses (PmRs) in 42% (10 of 24 patients).

### ***Other AFM13 clinical studies***

A phase 2a clinical study of AFM13 in patients with HL started recruitment in the second quarter of 2015. The study enrolled 25 HL patients relapsed or refractory to treatment with Adcetris® (brentuximab vedotin) and/or anti-PD1 antibodies. Different dosing protocols of AFM13 were explored to allow for improved exposure in more heavily pre-treated patient populations. Final data was presented at the annual conference of the American Society of Hematology in December 2020. The overall response rate was 16.6% (95% CI, 4.5-36.1%). Twelve-month PFS and OS estimates were 12.6% (95% CI, 3.2 - 28.9%) and 62.0% (95%, CI 39.6 - 78.1) respectively. Treatment with AFM13 was deemed to be well tolerated.

### ***AFM13-101 phase 1 dose escalation clinical study***

From September 2010 to April 2013, we conducted a phase 1 clinical study of AFM13, AFM13-101, in patients with HL. All patients in this study suffered from heavily pre-treated relapsed/refractory disease and had documented progression of disease at study entry. The objectives of the study were to: determine the safety and tolerability of increasing doses of single cycles of AFM13 as a monotherapy; determine the maximum tolerated dose and optimal biological dose of AFM13; determine the pharmacokinetic (PK) profile of AFM13; analyze immunological markers, NK cell activity, NK cell markers, serum outcome markers and cytokine release; assess the immunogenicity, or ability to provoke an immune response, of AFM13; and assess the activity of AFM13. The phase 1 study was conducted in Germany and the United States. We submitted a CTA for the phase 1 study to the PEI in May 2010 and an IND application to the FDA in June 2010.

The study enrolled 28 patients (16 males, 12 females) in eight dose cohorts. In the dose escalation part, 24 patients received increasing doses of AFM13 ranging from 0.01 mg/kg to 7.0 mg/kg on a weekly dosing schedule for four weeks. In addition, four patients were treated with 4.5 mg/kg twice weekly for four weeks. Of the 28 patients, 14 had refractory disease and the remainder had relapsed disease. The patients had received a median of six (range three to 11) previous lines of therapy for HL. Nine patients had previously received Adcetris®.



The clinical results were first presented to the medical community by Professor Andreas Engert, University Hospital of Cologne, the lead investigator for the study, at the Lugano International Meeting on Malignant Lymphoma in 2013. AFM13 showed an acceptable safety profile. An independent data monitoring committee, or IDMC, was responsible for the review of safety data on an ongoing basis. It was concluded that the maximum feasible single dose of 7 mg/kg was reached without any toxicity concerns, and consequently the maximum tolerated dose was not reached. The four patients who were treated with 4.5 mg/kg twice weekly completed treatment without raising any toxicity concerns for the IDMC. The most common adverse events were fever and chills, and in general, they were of mild to moderate severity. Overall, less than 30% of all adverse events were severe.

Of the 28 patients, 26 were eligible for efficacy evaluation. For the remaining two patients, efficacy assessments have not been performed. Of the 26 patients, three had a partial remission, 13 had stable disease and 10 had disease progression as best overall response. With the exception of the 0.04 mg/kg dose cohort, anti-tumor activity was observed at all dose levels tested but was more pronounced at or above 1.5 mg/kg. In this subgroup (n=13), 3 partial responses (>50% tumor shrinkage) and 7 cases with stable disease were observed, with an overall response rate of 23% (3/13) and a disease control rate of 77%.

Six of seven patients refractory to Adcetris® as their most recent treatment experienced stabilization of disease, or SD, following AFM13 treatment. One experienced progressive disease, or PD. Certain biomarkers indicated dose-dependent effects suggesting most active doses at or above 1.5 mg/kg. PK data were assessed in patients of all dosing cohorts. A dose proportional increase of systemic exposure (AUC<sub>0-</sub> (or Area Under the Curve from zero to infinity in a plot of the concentration of the drug in blood plasma against time, which represents the total drug exposure over time) and C<sub>max</sub> (or the maximum (or peak) concentration of the drug measured in plasma after the drug has been administered)) was observed. AFM13 was detectable in peripheral blood up to 168 hours post infusion in the highest dosing cohort. The mean half-life (t<sub>1/2</sub>) for dose cohorts 1.5 mg/kg and above was 9-19 hours. AFM13 treatment resulted in an increase of activated NK cells, which are characterized by CD69 expression on their surface. There was a trend showing that higher doses result in a more pronounced increase of CD69+ NK cells. Moreover, CD69 levels rose after AFM13 administration and fell to about baseline prior to the next dose (see figure below), indicating a pattern that reflected the PK of AFM13. All 28 patients in the study had measurable levels of soluble CD30 (sCD30), at the start of AFM13 treatment. sCD30 is shed by the tumor and is/was measurable in peripheral blood. In 24 patients the level was decreased at the end of treatment. Patients treated in dose cohorts 1.5 mg/kg and higher all had a marked decrease of sCD30.

Based on the phase 1 data we concluded, together with experts and authorities, that AFM13 has a favorable safety profile. In addition, AFM13 showed activity in terms of tumor response and pharmacodynamics (PD), even in Adcetris® refractory patients. However, PK and PD indicate that the dose regimen has to be optimized and that the measured clinical effect is likely to underestimate the potency of AFM13 in HL. Consequently, it was determined that in the phase 2a proof of concept study, the AFM13 dose had to be 1.5 mg/kg, be administered more frequently, at least for a certain time; the treatment duration had to be longer than four weeks; and a second cycle had to be mandated in patients that showed benefit from AFM13 treatment in the first cycle, i.e., complete response, partial response or SD.

## AFM24

### Overview

We are developing AFM24, a tetravalent, bispecific EGFR and CD16A-binding innate cell engager, for patients with advanced cancers known to express EGFR. AFM24 is engineered to broadly treat EGFR-expressing solid tumors through innate immune cell activation, potentially avoiding safety and mutational status limitations, as well as resistance mechanisms associated with other therapies. AFM24 is unique in that it activates innate immunity to kill solid tumors by inducing both antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as compared to other therapies that rely heavily on signal or checkpoint inhibition. We have successfully completed a toxicology study in cynomolgus monkeys at a range of dose levels up to 75mg/kg over 4 weeks with no observed toxicities even at high dose levels. In contrast, Cetuximab, an approved anti-EGFR antibody, revealed significant toxicity at the same dose-range.

### ***Clinical development of AFM24 as monotherapy***

In November 2019, our IND application for AFM24 cleared the required 30-day review by the FDA and is in effect for a phase 1/2a clinical trial of AFM24 in patients with advanced cancers known to express EGFR. We also received regulatory approval to commence a clinical trial of AFM24 from the UK and Spain. The initial goal of the study is to determine the maximum tolerated dose and recommended phase 2 dose of AFM24, as well as to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy in patients with advanced cancers known to express EGFR. The dose expansion phase of the study is intended to collect preliminary evidence of efficacy and to further confirm the safety of AFM24 as a monotherapy in patients with select solid tumor subtypes. The study started enrolling patients in the second quarter of 2020 and a weekly dose of 480 mg has been identified as the recommended phase 2 dose based on a comprehensive review of safety, pharmacokinetic and pharmacodynamic data, including exposure and NK cell CD16A receptor occupancy. A maximum tolerated dose has not been determined. AFM24 monotherapy showed a well-manageable safety profile. Three expansion cohorts have been initiated at the recommended Phase 2 monotherapy dose including Renal cell carcinoma (clear cell), failing standard of care (SoC) including TKIs and PD1/PD-L1 targeted therapy; Non-small cell lung cancer (EGFR-mutant), failing SoC TKIs; and Colorectal cancer, failing chemotherapy plus VEGF- and EGFR-targeted antibodies. We expect to report interim data from certain monotherapy expansion cohorts during the second or third quarter of 2023.

### ***Clinical development of AFM24 in combination with adoptive NK cells***

In March 2021, the FDA cleared an IND application we co-sponsored with NKGen Biotech (formerly known as NKMax America) to initiate a first-in-human phase 1/2a study of AFM24 in combination with SNK01 NK cells in patients with advanced cancers known to express EGFR. The goal of this study is to determine the safety, pharmacokinetics and pharmacodynamics, as well as the maximum tolerated dose and recommended phase 2 dose, of AFM24 in combination with SNK01 NK cells. We initiated enrollment in the study in November 2021 and expect to report interim data from the study in the second or third quarter of 2023.

The study is conducted pursuant to a clinical collaboration agreement we signed with NKGen Biotech in October 2020. Under the agreement, the two companies will contribute their respective product candidates and resources for the clinical trial. The clinical trial will combine NKGen Biotech's SNK01 (enhanced natural killer cells) with AFM24 in the autologous setting. The cost of the clinical study will be shared by Affimed and NKGen Biotech. The agreement also provides for the opportunity to pursue further clinical study combinations with additional product candidates from both parties.

In addition, in November 2020, we entered an R&D collaboration with Artiva Biotherapeutics to assess the feasibility and preclinical activity of combinations of Artiva's allogeneic NK cell product AB-101 and Affimed's ICE<sup>®</sup> molecules, building on earlier preclinical studies demonstrating synergistic cytotoxic activity.

Under the agreement, AFM24 and other undisclosed targets were combined with Artiva's GMP-grade allogeneic NK cells during the cell manufacturing process. The pre-manufacturing process included the loading of AB-101 with Affimed ICE<sup>®</sup> molecules prior to cryopreservation, creating specifically targeted allogeneic cells without the requirement for viral transduction. The resulting cryopreserved, off-the-shelf, targeted allogeneic NK cell products were assessed for anti-tumor activity and development potential. The costs of manufacturing and preclinical assessments are shared by both companies. The agreement provides for potential further development of selected combination products.

***Clinical development of AFM24 in combination with checkpoint inhibitors***

In February 2021, we entered into a clinical research collaboration with Roche to explore the combination of AFM24 with Roche's PD-L1 checkpoint inhibitor atezolizumab (Tecentriq<sup>®</sup>). Pursuant to the collaboration, we are funding and conducting a phase 1/2a clinical trial to investigate the combination of AFM24 and atezolizumab for the treatment of advanced EGFR expressing malignancies in patients whose disease has progressed after treatment with previous anticancer therapies. Roche supplies us with atezolizumab for the clinical trial. The phase 1/2a study will establish a dosing regimen for the combination therapy and assess safety and potential activity of AFM24 in combination with atezolizumab. We initiated enrollment in the study in December 2021. Interim data from the dose escalation portion of the study were reported at the 37<sup>th</sup> annual Meeting of the Society for Immunotherapy of Cancer in November 2022. Among three patients evaluated in the first dose escalation cohort treating patients with 160 mg of AFM24 weekly combined with atezolizumab biweekly, clinical activity was observed in two patients, while one patient awaited tumor assessment at cut-off date. One ongoing confirmed partial response was observed in a patient with gastric cancer and skin metastases who had rapidly progressed following four prior lines of therapy, including a PD-1 inhibitor, and an ongoing stable disease at 4+ months with symptomatic improvement was observed in a patient with pancreatic adenocarcinoma. Dose escalation was completed during the first quarter of 2023 with a weekly AFM24 dose of 480 mg confirmed as the recommended phase 2 dose. The phase 2 expansion phase of the study was initiated in the first quarter of 2023. We expect to report data from the dose escalation portion of the clinical study during the second or third quarter of 2023.

**AFM26 (Genentech: RO7297089)**

We have also developed AFM26, an innate cell-engaging bispecific antibody targeting B cell maturation antigen (BCMA) to address the medical need for a novel approach to treat multiple myeloma. In August 2018, Affimed announced a collaboration with Genentech, a Roche Group company, to investigate AFM26, renamed RO7297089, in BCMA-positive multiple myeloma patients who are refractory to standard-of-care therapies. Data presented at AACR 2020 on RO7297089 provided preclinical characterization of a novel BCMA/CD16A ICE<sup>®</sup> and showed that RO7297089 is a potent therapeutic agent in vitro and selectively kills BCMA expressing multiple myeloma tumor cells by activating innate immunity (ADCC and ADCP). The in vitro assessment demonstrated that, unlike T cell redirecting therapies, RO7297089 is unlikely to have a risk of acute cytokine release. In a one-month repeat-dose study in cynomolgus monkeys, RO7297089 was well tolerated, and there were no test article-related adverse effects at up to 50 mg/kg, with no significant cytokine release. In the phase 1 study, treatment with RO7297089 was well-tolerated at the dose levels tested, although infusion-related reactions necessitated long infusion duration for the first dose. Activity has been observed to date with partial responses at doses up to 1080 mg. There were no DLTs and a recommended phase 2 dose has not been identified. Genentech has decided not to progress with clinical development of RO7297089.

## **AFM28**

AFM28 is designed to bind to CD123, an established target in myeloid malignancies. We chose CD123 as it is almost universally expressed on leukemic blasts and leukemic stem cells in patients with AML, both at diagnosis and at relapse, and independently of cytogenetic risk. AFM28 is being developed for the treatment of patients with acute myeloid leukemia. AFM28 is currently in preclinical development, and we initiated recruitment into a first-in-human phase 1 study in Europe during the first quarter of 2023. Preclinical data suggest that AFM28 potently depletes primary CD123 + tumor cells via NK cell-mediated ADCC and promises to effectively target both leukemic blasts and leukemic stem cells (LSCs). High-binding affinity, potent NK-cell activation and target cell lysis with low risk of CRS suggest AFM28 is superior to previously developed Fc-enhanced anti-CD123 IgG and T cell-based therapies. In a cynomolgus toxicology model AFM28 was well-tolerated and demonstrated the anticipated pharmacodynamic activity.

## **Antibody generation at AbCheck**

AbCheck is our wholly owned, independently operated proprietary antibody screening platform company. AbCheck discovers and optimizes human therapeutic antibodies with a versatile technology platform for us as well as others on a fee for service basis. Tailored to the specific needs of its customers and their desired Target Product Profiles, AbCheck designs a personalized approach leveraging both cutting edge (e.g., microfluidics, rabbit mass humanization) and classical (e.g., phage/yeast display libraries) technologies to provide high quality leads. Flexibly adapting to AbCheck partners' needs, AbCheck has capabilities in multiple partnerships throughout the US and Europe by working with globally active pharmaceutical and biotechnology companies such as Tusk Therapeutics, bluebird bio, Eli Lilly, Daiichi Sankyo, Pierre Fabre and others.

## **Collaborations**

We have entered into strategic collaborations for some of our development programs. As part of our business development strategy, we aim to increase the number of our research collaborations in order to derive further value from our platforms and additionally exploit their potential. Key terms of our current material collaborations are summarized below.

### **Artiva Biotherapeutics**

#### *Overview*

On November 1, 2022, the Company entered into a collaboration agreement (the "Collaboration Agreement") with Artiva Biotherapeutics, Inc. ("Artiva") for the clinical development and commercialization of a combination therapy for any uses in humans or animals, comprising Affimed's product consisting of AFM13 and Artiva's product containing an NK cell referred to as "AB-101" (the "Artiva Product"). As of the effective date of the Collaboration Agreement, the following indications were included in the joint development plan: CD30+ Hodgkin Lymphoma and Peripheral T-Cell Lymphoma. While the collaboration is initially limited to the United States, the parties will, upon Affimed's request, in good faith discuss an expansion to certain other territories.

#### *Collaboration agreement*

Artiva has granted Affimed, with respect to the clinical development of the combination therapy an exclusive, and with respect to the promotion of the combination therapy under Collaboration Agreement a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free and non-sublicensable (with certain exceptions) license under Artiva patents and know-how Affimed has granted Artiva a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free license and non-sublicensable (with certain exceptions) license under Affimed patents and know-how for use in the clinical development of the combination therapy under Collaboration Agreement.

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Under the terms of Collaboration Agreement and the development plan agreed between the parties, Affimed will be primarily responsible for the development of the combination therapy, the conduct of the relevant clinical trials and the preparation and filing of regulatory materials during the clinical development. Artiva will support Affimed in the development, in particular through the supply of the Artiva Product and certain other products to be used in the clinical trials. Affimed will have the sole right and responsibility to promote the combination therapy according to a jointly aligned promotion plan.

Each party must use commercially reasonable efforts to perform the tasks assigned to it under Collaboration Agreement and the development plan. Affimed must also use commercially reasonable efforts to file an IND for the combination therapy and dose first patients within certain timeframes. In addition, each party must use commercially reasonable efforts to obtain and maintain regulatory approvals required to commercialize its product as part of the combination therapy. Each party must also use commercially reasonable efforts to supply its respective product in the quantities required for the clinical trials according to a jointly agreed clinical demand plan (which forms part of the development plan) as well as for commercialization according to jointly agreed commercial demand projections (which will be updated on a rolling quarterly basis during the commercial phase).

During the term of Collaboration Agreement, and subject to certain exceptions, neither party nor its affiliates is allowed to clinically develop or commercialize any product or therapy outside of the Collaboration Agreement comprising its product in the territory for any indication which is included in the development plan under Collaboration Agreement. In addition, during the term of Collaboration Agreement, and subject to certain exceptions, Affimed may not combine AFM13 with other NK cells, and Artiva may not clinically develop or commercialize the any product that directly and specifically binds to CD30.

The financial terms of Collaboration Agreement foresee that Affimed shall be responsible for all costs associated with the development of the combination therapy (including all clinical trial costs), except that Affimed and Artiva shall each bear 50% of the costs and expenses incurred in connection with the performance of any confirmatory clinical trial required by the FDA. Artiva shall be solely responsible for all costs incurred by Artiva for the supply of AB-101 and certain other products used in the clinical trials. In addition, under Collaboration Agreement, the parties have agreed to make payments to each other to achieve a proportion of 67%/33% (Affimed/Artiva) of revenues generated by both parties from commercial sales of each party's product as part of the combination therapy (such payment obligations to expire country-by-country upon expiry of collaboration patents and data exclusivity or upon biosimilar market entry).

Each party will own intellectual property that solely constitutes an improvement or enhancement to its respective background intellectual property. Other inventions generated in the performance of the development under Collaboration Agreement will be jointly owned by Affimed and Artiva. The clinical data generated in connection with the clinical trials under Collaboration Agreement shall be jointly owned, provided that prior to publication of such data, both parties are subject to certain usage restrictions of such data outside the collaboration.

The parties' collaboration will be overseen by a joint steering committee (the "JSC") with respect to the development and by a joint commercialization committee (the "JCC") with respect to the commercialization, each consisting of an equal number of representatives of Affimed and Artiva. If the JSC or JCC is unable to reach an agreement in a particular matter, the dispute shall be escalated to the joint executive committee (the "JEC") consisting of two executive members of either party. Affimed will have the final decision-making authority on the JEC, provided that certain matters (including the expansion of the development to additional indications and the adjustment of the protocol) require unanimous vote.

The Collaboration Agreement will expire if there is no payment obligation under Collaboration Agreement in the territory. Either party may terminate Collaboration Agreement in its entirety for any uncured (within 60 days after notice) material breach of Collaboration Agreement by the other party or upon the other party's insolvency. In addition, Affimed may terminate Collaboration Agreement if the futility assessment in an already pending trial for the Artiva Product is not passed.

Both parties may (during certain time windows during the development phase, but only before initiation of a confirmatory clinical trial for the combination therapy) opt out of the further development and promotion of the combination therapy. If a party opts out, the other party may continue the development and promotion of the combination therapy, in which case the opting-out party is required to provide certain continued support activities (e.g., supply of its product), and the revenue ratio applicable to each party shall be adjusted. In addition, if Affimed opts out, Affimed will be compensated for a portion of its costs incurred before the opt-out through a buy-down payment from Artiva (which will not become payable if Affimed opts out after a change of control of Affimed).

## **Roivant Sciences**

### *Overview*

On November 9, 2020, we announced that we entered into a license and strategic collaboration agreement with a subsidiary of Roivant Sciences Ltd. (“Roivant”) to develop and commercialize novel ICE<sup>®</sup> molecules, including AFM32, in oncology. Under the terms of the agreement, we received \$60 million in upfront consideration, comprised of \$40 million in cash and pre-paid R&D funding, and \$20 million of newly issued shares in Roivant. We are eligible to receive up to an additional \$2 billion in milestones over time upon achievement of specified development, regulatory and commercial milestones, as well as tiered royalties on net sales.

### *Research collaboration and license agreement*

Pursuant to the Roivant Agreement, Affivant Sciences GmbH (“Affivant”) was created and is primarily responsible for clinical development and commercialization worldwide in respect of each product candidate, while we will collaborate in the discovery and research phases of molecule development. Each product candidate will be developed pursuant to a research program (“Research Program”) and conducted by a joint project team, which will be overseen by a joint steering committee (the “JSC”), consisting of an equal number of representatives of Affivant and our company. If the JSC is unable to reach agreement on a particular matter, Affivant will generally have final decision-making authority, provided that the JSC may not decide on matters that (i) relate exclusively to the use of our innate cell engaging ROCK<sup>®</sup> technology platform as generally applied and not specifically applied to any licensed antibody products developed under their corresponding Research Program and directed, as applicable, to the lead target or any additional Affivant targets or (ii) would increase the then current number of full-time equivalents (“FTEs”) that we have assigned to the performance of the research plan for a certain Research Program by more than a certain number of additional FTEs. Except with respect to the activities being conducted by Affivant and us under the Research Programs and subject to our co-promotion option, Affivant shall have sole responsibility for, and bear all costs for, researching, developing and commercializing each product candidate, including all regulatory matters in relation thereto. The Research Programs will be funded by Affivant through an upfront payment to us.

We are subject to certain effort requirements in connection with our research activities under the Roivant Agreement, provision of technical assistance to Affivant and agreement with Affivant upon designation of the exclusive targets. Affivant must use diligent efforts to clinically develop and commercialize at least one licensed product that binds to each exclusive target in the United States, the European Union or Japan.

Affivant will own intellectual property that solely relates to the composition, method of use or manufacture of the any antibody product directed against the designated targets. We will own intellectual property that is an improvement of or otherwise solely relates to our innate cell engaging ROCK<sup>®</sup> technology. Other newly developed intellectual property will either be owned solely by a party if that party solely developed it or will be jointly owned by us and Affivant if developed by both parties.

The Roivant Agreement will expire on a country-by-country basis and licensed product-by-licensed product basis when there is no remaining royalty payment or other payment obligation in such country with respect to a licensed product. Either party may terminate the Roivant Agreement in its entirety, or with respect to a particular target, for any uncured material breach of the Roivant Agreement by the other party. Either party may also terminate the Roivant Agreement upon the other party's insolvency.



Affivant also has the right to unilaterally terminate the Roivant Agreement in its entirety, in its sole discretion, upon certain advance written notice. If the Roivant Agreement is terminated in its entirety, either by Affivant for convenience or by Affirmed for Newco's uncured material breach or bankruptcy, Affirmed has a right to negotiate commercially reasonable terms under which Affivant grants to Affirmed a license to the licensed products with respect to any exclusive target existing as of such termination date. If Affirmed does not agree with Affivant on such terms, the dispute will be settled by arbitration.

## **Genentech**

### *Overview*

On August 24, 2018 we entered into a research collaboration and license agreement with Genentech, a member of the Roche Group, for the development and commercialization of certain product candidates that contain novel NK cell engager-based immuno-therapeutics to treat multiple cancers. Under the terms of the agreement, in the fourth quarter of 2018, we received \$96 million.

### *Research collaboration and license agreement*

Under the terms of the research collaboration and license agreement (for purposes of this subsection, the "Agreement"), we granted Genentech an exclusive, royalty-bearing, sublicensable worldwide license during the term of the Agreement and thereafter under patent rights and know-how to commercialize the licensed portfolio and any additional product candidates developed pursuant to the Agreement against the exclusive targets designated by Genentech. Genentech has granted us a non-exclusive, royalty-free, non-sublicensable, worldwide license under certain of its intellectual property solely to fulfill our research obligations under the Agreement.

In addition to the \$96 million in payments received in 2018, we are eligible to receive up to approximately \$5.0 billion in total milestone payments upon successful development and commercialization of all product candidates developed pursuant to the Agreement. Of the \$5.0 billion in milestone payments, approximately \$250 million relate to development activities, \$1.1 billion relate to receipt of regulatory approvals, and \$3.6 billion relate to achievement of specified thresholds of worldwide net sales. In addition, we are eligible to receive tiered royalties from Genentech on net sales of licensed product candidates on a product-by-product and country-by-country basis until the later of the date when there are no valid patent claims under our licensed patents covering such licensed product in the applicable country and the tenth anniversary of the date of first commercial sale of such licensed product in such country. In March 2019, we were informed that an initial pre-clinical milestone was approved by Genentech. On November 7, 2019, we also announced that Genentech exercised its final option for an exclusive target under the companies' collaboration agreement to develop and commercialize novel NK cell engager-based immuno-therapeutics generated by our ROCK<sup>®</sup> platform to treat multiple cancers. The target selection triggered a milestone payment, in an undisclosed amount, to us from Genentech. During 2020, Genentech initiated a phase 1 clinical study for RO7297089, which triggered an additional milestone payment in an undisclosed amount.

Under the terms of the Agreement, Genentech will be responsible for the majority of the research, development and commercialization costs incurred in respect of each product candidate. The development of each product candidate will be overseen by a joint project team, which will in turn be overseen by a joint research committee, or JRC, consisting of an equal number of representatives of Genentech and us. If the JRC is unable to reach agreement, Genentech generally has final decision-making authority, provided that the JRC may not increase or decrease costs dedicated to our research activities under any research plan without our consent.

We are subject to certain efforts requirements in connection with our research activities under the Agreement, provision of technical assistance to Genentech and agreement with Genentech upon designation of the exclusive targets. Genentech must use commercially reasonable efforts to develop and commercialize in one of the United States, European Union or Japan at least one licensed product that binds to each exclusive target.



We will own intellectual property that we solely develop under the Agreement or that predominantly relates to its antibody engineering platform or molecule fragments that bind to the NK cell. Genentech will own intellectual property that it solely develops under the Agreement or that predominantly relates to an antibody designed to solely bind to an exclusive target. Other newly developed intellectual property will be jointly owned by us and Genentech. The parties will jointly prosecute related patents and Genentech will make final decisions regarding prosecution of patents that claim exclusive targets or relate to developed intellectual property that it solely owns under the Agreement and we will make final decisions regarding prosecution of patents that relate to developed intellectual property that we solely own under the Agreement.

The Agreement will expire on a country-by-country basis and licensed product-by-licensed product basis until there is no remaining royalty payment or other payment obligation in such country with respect to a licensed product. Either party may terminate the Agreement in its entirety, or with respect to a particular target, for any uncured material breach of the Agreement by the other party. Either party may also terminate the Agreement upon the other party's insolvency. Genentech also has the right to unilaterally terminate the Agreement in its entirety or with respect to a particular target, in its sole discretion, upon certain advance written notice. If the Agreement is terminated in its entirety or with respect to a particular exclusive target, either by Genentech for convenience or by us for material breach, we have a right to negotiate commercially reasonable terms under which Genentech grants to us (i) the right to transfer licensed products under any terminated exclusive target to us and (ii) a license for Genentech's intellectual property to such licensed products for further commercialization of such licensed products. If we do not agree with Genentech on such terms, the dispute will be finally settled by arbitration.

During the second quarter of 2021, Genentech informed Affimed that the Phase 1 study of RO7297089 (anti-BCMA/CD16A) was discontinued. A portion of these potential milestone payments are associated with that molecule.

### **MD Anderson Cancer Center**

In December 2020, we entered into a patent and technology license agreement with MD Anderson Cancer Center (the "MDACC License Agreement"), for the development and commercialization of certain novel oncology therapeutics resulting from the combination of cord blood-derived natural killer cells (CBNKs) and ICE<sup>®</sup> molecules, including AFM13. Under the terms of the MDACC License Agreement, we were granted an exclusive, royalty-bearing, sublicensable worldwide license during the term of the MDACC License Agreement to develop, manufacture and commercialize combination products requiring MDACC's patent rights and know-how. Pursuant to the MDACC License Agreement, we paid MDACC a nonrefundable upfront license fee, and MDACC is eligible to receive payments for development, regulatory and commercial milestones on a product-by-product basis. Milestone payments include, (i) for AFM13, up to \$27 million in development milestones, \$52.5 million in regulatory milestones and \$90 million in commercial milestones, and (ii) for any other combination product, up to \$14.25 million in development milestones, \$26.25 million in regulatory milestones and \$45 million in commercial milestones. MDACC is also eligible to receive low single-digit, tiered royalties on net sales of products developed pursuant to the MDACC License Agreement. MDACC is also eligible to receive certain payments pursuant to any sublicense of our rights under the MDACC License Agreement.

We are subject to certain efforts requirements in connection with our research and commercialization activities under the MDACC License Agreement.

MDACC, at its own cost, shall have control over the filing, prosecution, maintenance, and enforcement of any patents or patent applications under the Patent Rights.

The MDACC License Agreement will expire on the later of (i) December 2060 or (ii) expiration, on a country-by-country basis, of all licensed patents and the cancellation, withdrawal, or express abandonment of all licensed patent applications. MDACC may terminate the MDACC License Agreement upon our bankruptcy or insolvency. We may also terminate the agreement unilaterally upon certain advance written notice.

## **The Leukemia & Lymphoma Society**

*Overview.* In 2013, we entered into a research funding agreement with The Leukemia & Lymphoma Society, or LLS, for the clinical development of AFM13. Pursuant to the research funding agreement, LLS agreed to co-fund the clinical phase 2a development of AFM13 and to contribute up to approximately \$4.4 million over two years to support the project. We agreed to match LLS's contributions toward the project budget. Our receipt of the \$4.4 million total that LLS has agreed to contribute is conditioned on the achievement of certain milestones in connection with the development of AFM13. All milestones have been met and we have received \$4.4 million in funds from LLS. We also have retained exclusive commercialization and distribution rights to AFM13. In June 2016, the research funding agreement was amended to reflect a shift to the development of combination therapeutic approaches so that the milestones now relate primarily to the development of AFM13 as a combination therapy.

*Intellectual property and licenses.* Each party owns inventions made and data and know-how generated exclusively by such party or its affiliates prior to and during the term of the research funding agreement relating to the AFM13 development program. If any of such data, inventions and know-how is jointly made, it is jointly owned. LLS grants us an exclusive, worldwide, fully paid-up license to its rights in any such joint inventions and any invention made by any LLS employee resulting from the AFM13 development program for purposes specified in the research funding agreement. We have granted LLS an exclusive license to AFM13 that is only effective if we have ceased, or ceased commercially reasonable efforts with respect to, research, development and commercialization of all AFM13 products for a specified period, which period may be extended. As an alternative to this license, we may elect to pay LLS a payment equal to the amount that LLS actually funded to us plus interest. LLS has agreed to make reasonable adjustments and accommodations to this license in the event it impedes our ability to seek a partner to commercialize AFM13.

*Royalties.* In consideration of LLS's payments to us, we have agreed to pay LLS a mid-single digit royalty on net sales of products containing AFM13 until we have paid LLS a low single digit multiple of the funding they provided to us. After we have reached this initial royalty cap, we will pay LLS a sub-single digit royalty on net sales until the earlier of (i) the expiration of the last to expire patent covering the AFM13 products and (ii) ten years after the initial royalty cap is satisfied. These royalty payments are calculated on a country-by-country and product-by-product basis. We have also agreed to make certain low-to-mid-single digit royalty payments to LLS in the event of certain transfers of rights to any product containing AFM13 or in the event we undergo certain change of control transactions, in each case up to the royalty cap described above.

*Term and termination.* Unless earlier terminated pursuant to the terms of the agreement, the research funding agreement terminates when there are no longer any payment obligations owing from one party to another. The research funding agreement may be terminated by either party for the other party's material breach, material violation of applicable law, or if a representation or warranty made by the other party in the research funding agreement is not true in any material respect, subject to a specified cure period. If LLS terminates for our default, our royalty obligations and the interruption license will survive such termination. Either party may terminate if the other party undergoes specified bankruptcy or insolvency-related events.

## Intellectual Property

### Overview

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to protect, for example, the composition of matter of our product candidates, their methods of use, the technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment and additional compositions created or identified from our technology platforms and ongoing development of our product candidates. Specifically, we seek patent protection in the United States and internationally for novel compositions of matter directed to aspects of the molecules, basic structures and processes for manufacturing these molecules and the use of these molecules in a variety of therapies.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary positions. To date, we have not identified any potential infringement of our patents by third parties.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates or use of our technology platforms. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

### Our Platforms and Programs

The patent portfolios for our most advanced programs are summarized below.

#### *AFM13*

We own and/or control a patent family that relates to the mode of action of AFM13, the recruitment of immune effector cells via a specific receptor. We filed a related PCT application in 2006. Any patents resulting from these patent applications, if issued, also will expire in 2026. Patents have been granted in Australia, Brazil, Canada, China, Hong Kong, India, Japan, Russia, Europe (France, Great Britain, Germany, Switzerland and Liechtenstein, Belgium, the Netherlands, Italy, Spain, Austria, Denmark and Sweden) and certain claims have been granted in the United States (expiry of the US patent in 2029).

In 2016 a patent application claiming a combination of AFM13 with PD-1 antibodies was filed. The respective PCT application is pending in Brazil, Canada, and India. Patents have been granted in Australia, Europe (validated in 37 contracting states including Austria, Belgium, Switzerland/Liechtenstein, Czech Republic, Germany, Denmark, Spain, Finland, France, Great Britain, Greece, Hungary, Ireland, Italy, Luxembourg, Monaco, Malta, Netherlands, Norway, Poland, Portugal, Sweden, San Marino und Turkey), China, Japan, Russia and the United States. An additional PCT application claiming a method for the production of AFM13 and the related product was filed in 2020 and respective issued patents will expire 2040. This application was nationalized/regionalized in Australia, Canada, Europe, India, Japan, South Korea, Singapore, Hong Kong, and the US.

Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g. AFM13 and the respective issued patents will not expire before 2039. This application was nationalized/regionalized in Australia, Brazil, Canada, China, Hong Kong, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, the United States and South Africa. A patent family is jointly owned and/or controlled with Artiva directed to the combination of AFM13 with Artiva's NK cell line AB-101, and respective issued patents will not expire before 2042.

*AFM24*

We own and/or control patents that cover our EGFR/CD16A compound. As is the case for AFM13, these include a patent family relating to the recruiting of immune effector cells via a specific receptor, which will expire in 2026, generally, and in 2029 in the United States. Patents have been granted in Australia, Brazil, China, India, Russia, Europe (France, Great Britain, Germany, Switzerland and Liechtenstein, Belgium, the Netherlands, Italy, Spain, Austria, Denmark, and Sweden) and in the United States. In 2019, a PCT patent application was filed which relates to the specific AFM24 compound. Patents in this family have been granted in the United States and South Africa. National phases of the application are pending in Europe, the United States, Canada, Mexico, Brazil, Russia, China, Hong Kong, Singapore, South Korea, Israel, Australia, New Zealand, Japan, and India. Any patents resulting from these patent applications, if issued, will expire in 2039.

Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g., AFM24 and the respective issued patents will not expire before 2039. This application was nationalized/regionalized in Australia, Brazil, Canada, China, Hong Kong, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, the United States and South Africa.

*AFM26*

We have out licensed the patents which cover our BCMA/CD16A compound. These include a patent family directed to BCMA/CD16A TandAb constructs pending in Australia, Canada, China, Europe, Japan and the United States. In 2019 a patent application was filed which relates to specific multivalent antibody constructs and the specific AFM26 compound. The application was nationalized in Argentina, Taiwan, the Gulf Cooperation Council, United States, Australia, Brazil, Canada, Chile, Costa Rica, Israel, Iran, Malaysia, China, Columbia, Egypt, Europe, India, Indonesia, Japan, South Korea, Mexico, Peru, Philippines, Singapore, South Africa, Thailand, Ukraine, and Vietnam. Any patents resulting from these patent applications, if issued, will expire in 2039. In the United States and China patents specific for the AFM26 compound have been granted.

Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g., AFM26 and the respective issued patents will not expire before 2039. This application was nationalized/regionalized in Australia, Brazil, Canada, China, Hong Kong, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, the United States and South Africa.

*AFM28*

We own and/or control a patent application relating to specific multivalent antibody constructs and claims the format of the AFM28 compound in the generic manner of the ROCK<sup>®</sup> platform. The application was nationalized in Argentina, Taiwan, the Gulf Cooperation Council, United States, Australia, Brazil, Canada, Chile, Costa Rica, Israel, Iran, Malaysia, China, Columbia, Egypt, Europe, India, Indonesia, Japan, South Korea, Mexico, Peru, Philippines, Singapore, South Africa, Thailand, Ukraine, and Vietnam. Any patents resulting from these patent applications, if issued, will expire in 2039.

Additionally, we also own and/or control a patent portfolio, which includes one patent family directed to the compound of AFM28. The non-provisional patent application was filed in 2022 with pending applications in Argentina, Taiwan and a PCT application and issued patents will not expire before 2042.

Moreover, we own and/or control a patent family that relates to cryopreserved NK cells preloaded with an ICE<sup>®</sup>, e.g., AFM28 and the respective issued patents will not expire before 2039. This application was nationalized/regionalized in Australia, Brazil, Canada, China, Hong Kong, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, the United States and South Africa.

### *ROCK<sup>®</sup> platform*

We own and/or control our immune cell engager platform patent portfolio. This includes a patent family that covers multivalent antibody constructs comprised of four variable domains which are fused by linkers in different length. The claims with regard to use of such immune cell engager antibodies cover general diagnostic and therapeutic use, in particular for viral, bacterial or tumoral diseases. These patents expired in 2019 and were granted in Australia, Canada, certain countries in Europe, Japan and the United States. Another pending patent application covers immune cell engagers that have a different immune cell engager structure which shows increased potency. The application is currently pending in Australia, Brazil, Canada, China, Europe, Japan, Mexico, Russia, and the United States and if issued the patent will expire in 2030. Closely related to the immune cell engager platform is the Flexibody format, which is covered by a patent family fully owned by us, granted in Europe and Japan. A U.S. application in this family is still pending. These patents and applications (if issued) will expire in 2021. The latest patent application relating to specific Fc-comprising ROCK<sup>®</sup> antibody constructs, which claims the generic format of AFM26, AFM28 and AFM32 as well as the specific AFM26 compound was filed in 2019. The application was nationalized in Argentina, Taiwan, the Gulf Cooperation Council, United States, Australia, Brazil, Canada, Chile, Costa Rica, Israel, Iran, Malaysia, China, Columbia, Egypt, Europe, India, Indonesia, Japan, South Korea, Mexico, Peru, Philippines, Singapore, South Africa, Thailand, Ukraine, and Vietnam. Any patents resulting from these patent applications, if issued, will expire in 2039.

An additional, recently developed variant of an ICE<sup>®</sup> in a ROCK<sup>®</sup> platform format is the *Duplexbody* format. A PCT application claiming this format was filed in 2022 and respectively granted patents would expire in 2042.

### *Trispecific Antibodies*

Another platform development effort resulted in the successful generation of a trispecific antibody format, for which we submitted a patent application in 2015 and applications are pending in Brazil, Canada, China, , India, Mexico, South Korea, and the U.S. in 2015. Patents based on this application have been granted in Australia, Europe (patent maintained after opposition), Japan and South Africa. Another International PCT-application was filed in 2016 for further trispecific antibody formats. These patent applications were submitted to cover several dimeric and trispecific antibody formats which are based on variable domains characterized by a common specific dimerization pattern. While applications are pending in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Mexico, Singapore, and South Korea, respective patents have been granted in Japan, Russia, the United States and South Africa and such patents will expire in 2036.

Additionally, a further trispecific ICE<sup>®</sup> platform (Trispecific Binders) was developed and a respective non-provisional patent application was filed in 2021 with national/regional applications pending in Australia, Canada, China, Europe, Israel, India, Japan, the United States and South Africa.

### *Novel Multivalent Bi- and Trispecific Antibody Formats*

We are exploring various multivalent, bi- and trispecific immune cell engagement formats designed to prolong both serum PK and pharmacodynamics.

### ***In-Licensed Intellectual Property***

We have entered into exclusive as well as non-exclusive patent and know-how license agreements which grant us the right to develop, use and commercialize our immune cell engager antibody platform and product candidates derived thereof. The licenses include obligations to pay development milestones and sales royalties on products we develop and commercialize that were generated using patented technologies.

### **FDA Regulatory Review Process**

The Hatch-Waxman Act permits a patent term extension for FDA-approved drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in other jurisdictions to extend the term of a patent that covers an approved drug, or to offer similar protection for an extended period, as is the case in the European Union. In the future, if and when our pharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

### **Trade Secrets**

We also rely on trade secret protection for our confidential and proprietary information. Included in our trade secrets are various aspects of our manufacturing process that we conduct in cooperation with contract manufacturers.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, contractors and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, contractors, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. German law provides that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions.

### **Manufacturing**

We express our tetravalent bispecific ICE<sup>®</sup> product candidates in mammalian cells and develop our production processes on a laboratory scale. The research grade material made in our laboratories is suitable for conducting compound profiling activities. In the course of preclinical development, we transfer the process to external manufacturers (Contract Manufacturing Organizations, or CMOs) which we select according to a standardized operating procedure. Before and during the cooperation with a CMO we conduct audits to assess quality and compliance with the mutually agreed process descriptions and current Good Manufacturing Practice (GMP) regulations. The CMOs themselves are controlled by their in-house quality assurance functions and inspected by regulatory agencies, including EMEA and the FDA.

The technology transfer generally includes several different aspects: the development of a production cell line, the development of research, master and working cell banks, the development and qualification of upstream and downstream processes, the development of the drug product form and process and the development of suitable validated analytical methods for test and release, as well as stability testing. During the development of our drug candidates, our CMOs scale the manufacturing process to suitable size. Such upscaling typically takes several steps and may involve modification of the process, in which case comparability of the resulting material to earlier preclinical and clinical material must be demonstrated to the relevant authorities before proceeding with further clinical studies. From our CMOs we receive process development-derived material for preclinical testing and material meeting GMP standards for clinical supplies.



We rely on and will continue to rely on CMOs for both drug substance and drug product. We seek to establish a good relationship in order to expeditiously solve problems should they arise. Our contract manufacturers have extensive capacities and a certain flexibility to adjust to demand. Likewise, our manufacturers purchase and stock materials required for production usually from multiple sources and should therefore be less vulnerable to potential shortages. Generally, we need to commit to certain manufacturing slots and capacities in advance, which typically involves the payment of reservation fees.

We have successfully scaled up the processes for AFM13, AFM24, and AFM28 and manufactured material to meet the clinical drug supply demands for our clinical studies. We are currently working with several external companies to establish a manufacturing process with a productivity adequate for the commercial phase.

### **Commercialization**

We have not yet established a sales, marketing or product distribution infrastructure because our lead product candidate is still in clinical development.

Prior to receiving marketing approvals, we plan to build a focused sales and marketing organization to sell our products if and when marketing approval is granted. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our salesforce. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with thought leaders in relevant fields of medicine.

### **Competition**

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are many companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work, among others, either by using next-generation antibody technology platforms or by new immunological approaches to address specific cancer targets. These treatments are often combined with one another in an attempt to maximize the response rate. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule, as we are.

Clinical phase 2 data with the anti-PD-1 CPIs nivolumab and pembrolizumab in HL have been published. These data indicate that treatment with anti-PD-1 antibodies results in high response rates in the salvage setting of HL. In 2016, the FDA granted accelerated approval, and the European Commission granted approval for nivolumab in classical HL patients who have relapsed or progressed after autologous hematopoietic stem cell transplantation and brentuximab vedotin (Adcetris®). In 2017, the FDA granted accelerated approval, and the European Commission granted approval for pembrolizumab in adult and pediatric patients with refractory cHL who have relapsed after 3 or more prior lines of therapy, and the European Commission granted approval for pembrolizumab in adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin. In 2020, the FDA approved an expanded label for pembrolizumab in relapsed or refractory cHL. Phase 2 and phase 3 studies of brentuximab vedotin in combination with nivolumab are either planned or ongoing. If AFM13, alone or in combination, were to be approved for HL, we could be in competition with these therapies, as well as any other therapies or combination regimens that comprise the standard of care that our offering could potentially displace.



Bretuximab vedotin, or Adcetris<sup>®</sup>, an antibody-drug conjugate targeting CD30, was approved by the FDA in relapsed/refractory HL in 2011. In addition, Adcetris<sup>®</sup> was approved by the FDA in 2018 for the treatment of previously untreated Stage 3/4 cHL in combination with chemotherapy. In the European Union, Adcetris<sup>®</sup> is approved for similar indications. Adcetris<sup>®</sup> is also indicated for previously treated systemic anaplastic large cell lymphoma (ALCL), primary cutaneous ALCL, and CD30 positive mycosis fungoides, as well as for previously untreated systemic ALCL or other CD30 positive peripheral T-cell lymphomas in combination with chemotherapy in the US and for previously untreated systemic ALCL in Europe. Adcetris<sup>®</sup> is currently being investigated in various combinations in HL, including checkpoint inhibitors.

In late 2021, clinical data from an open label Phase 2 study of COPIKTRA<sup>®</sup> (duvelisib) in relapsed/refractory (R/R) PTCL was presented at the annual meeting of the American Society of Hematology. Both overall response and complete response rates were above that seen for other R/R PTCL agents at similar stages of development or with accelerated approval. On the strength of this data, duvelisib was added to the National Comprehensive Cancer Network treatment guidelines as a “Category 2a: Other Recommended Regimen” for PTCL, Initial Palliative Intent Therapy and for PTCL, Second-Line Therapy and Subsequent Therapy, for all PTCL subtypes. COPIKTRA<sup>®</sup> (duvelisib) is currently approved for Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL). In 2022, the FDA issued a warning that clinical trial results show a possible increase in risk of death from COPIKTRA. In 2023, the EMA granted an Orphan Drug Designation for duvelisib in PTCL in Europe. If AFM13, alone or in combination is approved for PTCL patients, we could be in competition with this and any other therapies or combination regimens that comprise the standard of care that our therapy could potentially displace

We expect that our ROCK<sup>®</sup> platform as well as our novel antibody formats derived from this platform will serve as the basis for future product candidates and collaborations with pharmaceutical companies. Other companies also have developed platform technologies that may compete with our platforms. For example, Dragonfly Therapeutics is developing TriNKET, which specifically activates cells of the innate and adaptive immune system and has recently started clinical development of one of these TriNKET assets. GT Biopharma is developing its TriKEs and TetraKEs platform designed to target natural killer cells and tumor cells forming an immune synapse between the NK cell and the tumor cell thereby inducing NK cell activation at that site, and recently started clinical development of multiple assets. Innate Pharma is developing several multi-specific NK cell engagers for oncology indications based on their ANKET platform. Cytovia is developing FLEX-NK bispecific antibodies to direct NK cells towards tumor targets. Furthermore, there may be other companies we have not identified that develop technologies that also engage NK cells in oncology, which would put them into competition with our therapies.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining top qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our therapeutic product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, our marketing capabilities, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop.

Our competitors also may obtain FDA, European Commission or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. The regulatory framework to approve biosimilar products has already been created in Europe and the United States.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates may compete with many existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates will not be competitive with them as such. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors.

In addition to currently marketed therapies, there are also a number of products in late stage clinical development to treat cancer. These product candidates in development may provide efficacy, safety, dosing convenience and other benefits that are not provided by currently marketed therapies or our drugs. As a result, they may provide significant competition for any of our product candidates for which we obtain marketing approval.

If our lead product candidates are approved for the indications for which we are currently undertaking clinical studies, they will compete with the therapies and currently marketed drugs discussed elsewhere in this document.

### **Government Regulation and Product Approval**

Government authorities in all major pharmaceutical markets extensively regulate, among other things, the research, non-clinical and clinical development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import and export of pharmaceutical products such as those we are developing. Although our initial focus will be on the United States and Europe, we will develop and seek marketing approval for our products also in other countries and territories, such as Canada or Japan, and for markets that follow the leading authorities, such as Brazil or South Korea. The processes for obtaining regulatory approvals in the United States, Europe and in other countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

### ***International Conference on Harmonization (ICH)***

The International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or the ICH, is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration. The purpose of ICH is to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines by recommending ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration. Harmonization would lead to a more economical use of human, animal and material resources, the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to protect public health.

ICH guidelines have been adopted as law in several countries. In many areas of drug development ICH has resulted in comparable requirements, for instance with respect to the Common Technical Document, or the CTD, which has become the standard dossier format for filings for market authorization in several jurisdictions. Thus, ICH has facilitated a more efficient path to markets.

## **FDA Approval Process**

All of our current product candidates are subject to regulation in the United States by the FDA as biological products, or biologics. The FDA subjects biologics to extensive pre- and post-market regulation. The Public Health Service Act (PHSA), the Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, non-clinical and clinical development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending BLAs, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or civil or criminal penalties.

The PHSA emphasizes the importance of manufacturing control for biological products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

The process required by the FDA before a new biologic may be marketed in the United States is long and expensive and due to the nature of biological products inherently uncertain. Biologics development in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND application which must become effective before clinical testing may commence. Furthermore, adequate and well-controlled clinical studies are required in order to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought. Developing the data to satisfy FDA marketing authorization requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory (GLP) principles. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical study protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before United States clinical studies may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA does not issue a clinical hold within this 30-day period, the clinical study proposed in the IND may begin.

Clinical studies involve the administration of the IND or biologic to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical studies must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical study sponsors, investigators, and monitors; as well as (iii) under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical study at any time, or impose other sanctions, if it believes that the clinical study either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical study participants. The study protocol and informed consent information for participants in clinical studies must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical study at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. The study sponsor may also suspend a clinical study at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical studies to support BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In phase 1, the biologic is initially introduced into healthy human subjects or patients and is tested to assess PK, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. In the case of some products for more severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. Phase 2 usually involves studies in a limited patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in phase 2 studies, phase 3 studies are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical study sites. These phase 3 clinical studies are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the biologic. Studies conducted outside of the US under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product licensing.

Sponsors of clinical studies for investigational drugs must publicly disclose certain clinical study information, including detailed study design and study results in NIH public ClinicalTrials.gov databases. These requirements are subject to specific timelines and apply to most controlled clinical studies of FDA-regulated products.

After completion of the required clinical testing, a Biologics License Application (BLA) is prepared and submitted to the FDA. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls and must demonstrate the safety and efficacy of the product based on these results. The BLA must also contain extensive manufacturing information. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs is additionally subject to a substantial application user fee, as well as annual product and establishment user fees, which may total several million dollars and are typically increased annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologics are reviewed within ten months from the date the application is accepted for filing. Although the FDA often meets its user fee performance goals, it can extend these timelines if necessary, and its review may not occur on a timely basis at all. The FDA usually refers applications for novel biologics many times to an advisory committee—typically a panel that includes clinicians and other experts—for review and evaluation of data concerning the safety and efficacy of marketed investigational drug products for use in the treatment of patients and makes appropriate recommendations to the FDA Commissioner. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic is manufactured. The FDA will not approve the product unless it verifies that compliance with cGMP standards is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission which requires substantial additional testing and / or information, in order for the FDA to reconsider the application. Once those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA if applicable regulatory criteria are not satisfied.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, effective, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. The extension of an approval for a biologic may be significantly more limited than initially requested in the application, which might restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions are included in the prescription leaflet. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) in order to track and thereby ensure that the benefits of the biologic outweigh the potential risks for patients. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS might materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval commitments, including, e.g., the testing and surveillance of the biologic's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or safety concerns are identified following initial marketing.

As part of the manufacturing process, the marketing authorization holder is required to perform specific tests for each drug substance and drug product batch before it is released for distribution. If the product is subject to official lot release by the FDA, marketing authorization holder has to submit specific release data of each product batch to the FDA together with a release protocol, showing a summary of previous release specification data from all the batches produced so far as well as the data from the current batch. The FDA may also perform certain confirmatory tests on batches of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. After approval of biologics, marketing authorization holder must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection.

#### *Expedited Program*

Speeding the availability of drugs that treat serious diseases are in everyone's interest, in particular when the drugs are the first available treatment or if the drug has advantages over existing treatments. The FDA has developed four distinct approaches to making such drugs available as rapidly as possible: a) Priority Review, b) Breakthrough Therapy, c) Accelerated Approval and d) Fast Track. In short:

- **Priority Review:** A Priority Review designation means that FDA's goal is to take action on the application within 6 months.
- **Breakthrough Therapy:** A process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.
- **Accelerated Approval:** These regulations allow drugs for serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint.
- **Fast Track:** This is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

#### *Biosimilars*

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009. That Act created an approval pathway authorizing the FDA to approve biosimilars. Biosimilars are biological products which are "highly similar" to a previously approved biologic product or "reference product" and for which there are no meaningful differences between the biosimilar product and the reference product in terms of analytics, safety, purity, potency and clinical efficacy. To date, several biosimilars have been approved under the BPCIA framework.

### *Advertising and promotion*

Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal and state civil and criminal investigations and prosecutions.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

### *Adverse event reporting and cGMP compliance*

Adverse event reporting and submission of periodic safety reports are required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, manufacturing, packaging, labeling, storage and distribution procedures must continue to conform to cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls, or impose marketing restrictions through labeling changes or product removals if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### *Orphan drug*

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular product to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different biologic for the same disease or condition, or the same biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

We have received orphan drug designation for AFM13 for the treatment of HL in the United States and Europe and for and T-cell lymphoma in the United States.



*Other healthcare laws and compliance requirements*

In the United States, our activities are potentially subject to regulation by federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (for example, the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments.

**EU Approval Process**

The EMA is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally-authorized medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the member states. The EMA draws on resources of over 40 National Competent Authorities (the NCAs) of EU member states. The Paul Ehrlich Institute, or PEI, is one of the NCAs for Germany, and regulates, among others, antibody products.

The process regarding approval of medicinal products in the European Union follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical study application or CTA for each study in humans, which must be approved before the study may begin;
- performance of adequate and well-controlled clinical studies to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a Marketing Authorization Application or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced current Good Manufacturing Practices;
- potential audits of the non-clinical and clinical study sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

*Preclinical studies*

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.



### *Clinical study approval*

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical studies in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of each EU member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents. Furthermore, a clinical study may only be started after a competent ethics committee has issued a favorable opinion on the clinical study application in that country.

Manufacturing and import into the EU of investigational medicinal products is subject to the holding of appropriate authorizations and must be carried out in accordance with current Good Manufacturing Practices.

### *Health authority interactions*

During the development of a medicinal product, frequent interactions with the health authorities are important to ensure all relevant input and guidelines/regulations are taken into account in the overall program. We have had several interactions with the FDA as well as European competent authorities (both national and EMA) at key timepoints in the development of our antibody products.

### *Paediatric studies*

Regulation (EC) 1901/2006, which came into force on January 26, 2007, aims to facilitate the development and accessibility of medical products for use in children without subjecting children to unnecessary studies, or delaying the authorization of medicinal products for use in adults. The regulation established the Paediatric Committee, or PDCO, which is responsible for coordinating the EMA's activities regarding medicines for children. The PDCO's main role is to determine all the studies that marketing authorization applicants need to do in the pediatric population as part of the so-called Paediatric Investigation Plans, or PIPs. All applications for marketing authorization for new medicines that were not authorized in the European Union before January 26, 2007 have to include either the results of studies carried out in children of different ages (as agreed with the PDCO), or proof that a waiver or a deferral of these studies has been obtained from the PDCO. As indicated, the PDCO determines what pediatric studies are necessary and describes them in a PIP. This requirement for pediatric studies also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PDCO can grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults and can also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a MAA can be filed, or an existing marketing authorization can be varied, the EMA checks that companies are in compliance with the agreed studies and measures listed in each relevant PIP.

Regulation (EC) 1901/2006 also introduced several incentives for the development of medicines for children in the EU:

- medicines that have been authorized across the European Union in compliance with an agreed PIP are eligible for an extension of their patent protection by six months. This is the case even when the pediatric studies' results are negative;
- for orphan medicines, the incentive is an additional two years of market exclusivity, extending the typical 10-year period to 12 years;
- scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of medicines for children; and
- medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate may be eligible for a paediatric use marketing authorization, or PUMA. If a PUMA is granted, the product will benefit from 10 years of market protection as an incentive for the development of the product for use in children.

The indications we pursue, especially those in certain hematologic malignancies, involve pediatric patients and we shall prepare PIPs at the appropriate time.

*Marketing authorization application*

Authorization to market a product in the EU member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. Since our products by their virtue of being antibody-based biologics fall under the mandatory scope of the centralized procedure, only this procedure will be described here.

*Centralized authorization procedure*

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. A successful application under the centralized authorization procedure results in a marketing authorization from the European Commission, which is automatically valid in all EU member states. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the Commission decision. The EMA and the European Commission administer the centralized authorization procedure.

Under the centralized authorization procedure, the CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion on an initial MAA within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. If the CHMP concludes that the quality, safety and efficacy of the medicinal product are sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

*Accelerated assessment procedure*

When an application is submitted for a marketing authorization in respect of a drug for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops. We believe that many of our product candidates may qualify for this provision and we will take advantage of this provision as appropriate.

*Conditional approval*

As per Article 14(7) of Regulation (EC) 726/2004, a medicine that would fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorization holder. These specific obligations are to be reviewed annually by the EMA. The list of these obligations shall be made publicly accessible. Such an authorization shall be valid for one year, on a renewable basis.

*Period of authorization and renewals*

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder shall provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variants introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the so-called sunset clause).

*Orphan drug designation*

Regulation (EC) 141/2000 states that a drug shall be designated as an orphan drug if its sponsor can establish:

- (a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or;
- (b) that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- (c) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation (EC) 847/2000 sets out criteria for the designation of orphan drugs.

An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation (EC) 141/2000 shall be eligible for incentives made available by the European Union and by the member states to support research into, and the development and availability of, orphan drugs.

We have applied for and been granted orphan status in the European Union for AFM13 for the treatment of HL.

### *Regulatory data protection*

Without prejudice to the law on the protection of industrial and commercial property, marketing authorizations for new medicinal products benefit from an 8+2+1 year period of regulatory protection.

This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of ten years plus an additional market exclusivity of one further year if, during the first eight years of those ten years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the reference product beginning eight years after first approval, but the third party may market a generic version only after ten (or eleven) years have lapsed.

As indicated, an additional period of exclusivity can be applied for when an applicant has complied with all requirements as set forth in an approved PIP.

### **International Regulation**

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical studies, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission approval.

### **Pharmaceutical Coverage, Pricing, and Reimbursement**

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers, and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our products.

The division of competences within the European Union leaves to Member States the power to organize their own social security systems, including health care policies to promote the financial stability of their health care insurance systems. According to Article 168 of the Treaty on the Functioning of the European Union or TFEU, "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care."

In this context, the national authorities are free to set the prices of medicinal products and to designate the treatments that they wish to reimburse under their social security system. However, the European Union has defined a common procedural framework through the adoption of Council Directive 89/105/EEC, which is generally known as the "Transparency Directive." This instrument aims to ensure that national pricing and reimbursement decisions are made in a transparent manner and do not disrupt the operation of the internal market.

The Pharmaceutical Pricing and Reimbursement systems established by Member States are usually quite complex. Each country uses different schemes and policies, adapted to its own economic and health needs. We would have to develop or access special expertise in this field to prepare health economic dossiers on our medicinal products if we would market our products, if and when approved, in the EU.

### **C. Organizational structure**

The registrant corporation Affimed N.V. has three direct or indirect wholly owned subsidiaries—Affimed GmbH, AbCheck s.r.o. and Affimed, Inc. that are each listed in Exhibit 8.1 filed hereto. We primarily operate our business out of our operating subsidiary, Affimed GmbH. AbCheck s.r.o. and Affimed, Inc. are direct subsidiaries of the operating subsidiary Affimed GmbH.

#### **D. Property, plant and equipment**

Our headquarters are in Heidelberg, Germany, where we occupy office and laboratory space at the Technologiepark (Technology Park). The majority of this space will expire in 2023 and the remaining space (less than 10%) in 2025. We signed a new lease contract for offices and laboratories in 2021 and we are planning to move to a new facility in Mannheim, Germany, approximately mid-2023. The contractual lease term is ten years including a cancellation option after five years with an expected start mid-2023. The terms provide for renewal options.

We also lease office and laboratory space in the Czech Republic that is contracted until December 2025 with a period of notice of three months.

We believe that our new facilities in Mannheim are adequate to meet current and future needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

#### **ITEM 4. UNRESOLVED STAFF COMMENTS**

Not applicable.

#### **ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

You should read the following discussion and analysis of our financial condition and results of operations together with the information in our consolidated audited financial statements, including the notes thereto, included in this Annual Report. The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB, which might differ in material respects from generally accepted accounting principles in other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those described under "Risk Factors" and elsewhere in this Annual Report.

##### **A. Operating Results Overview**

We are a clinical-stage immuno-oncology company focused on discovering and developing highly targeted cancer immunotherapies. Our product candidates are being developed in the field of immuno-oncology, which represents an innovative approach to cancer treatment that seeks to harness the body's own immune defenses to fight tumor cells. The most potent cells of the human defense arsenal are types of white blood cells called innate immune cells (Natural Killer cells, or NK cells and macrophages) and T cells. Leveraging our fit-for-purpose ROCK<sup>®</sup> platform, we develop proprietary, next-generation bispecific antibodies, so-called innate cell engagers, which are designed to direct and establish a bridge between innate immune cells and cancer cells. Our innate cell engagers have the ability to bring innate immune cells into proximity and trigger a signal cascade that leads to the destruction of cancer cells. Due to their novel tetravalent architecture (which provides for four binding domains), our innate cell engagers bind to their targets with high affinity and have half-lives that allow regular intravenous administration, with different dosing schemes being explored to allow for improved exposure in heavily pretreated patient populations. We believe, based on their mechanism of action and the preclinical and clinical data we have generated to date, that our product candidates, alone or in combination, may ultimately improve response rates, clinical outcomes and survival in cancer patients and could eventually become a cornerstone of modern targeted oncology care. Building on our leadership in the innate immune cell space, we are also developing novel tetravalent, bispecific antibody formats with the potential to tailor immune-engaging therapy to different indications and settings.

To date, we have financed our operations primarily through our public offerings of our common shares, private placements of equity securities, the incurrence of loans including convertible loans and through government grants and payments for collaborative research and development services. Through December 31, 2022, we have raised an aggregate of €570.4 million (gross proceeds) through the issuance of equity and incurrence of loans. To date, we have not generated any revenues from product sales or royalties. Based on our current plans, we do not expect to generate product or royalty revenues unless and until we or any collaboration partner obtain marketing approval for, and commercialize, any of our product candidates.

We have generated losses since we began our drug development operations in 2000. For the year ended December 31, 2022, we incurred a net loss of €86.0 million. As of December 31, 2022, we had an accumulated deficit of €430.2 million.

We expect to continue incurring losses as we continue our preclinical and clinical development programs, apply for marketing approval for our product candidates and, subject to obtaining regulatory approval for our product candidates, build a marketing and sales team to commercialize our product candidates. Our profitability is dependent upon the successful development, approval, and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional cash. We intend to fund future operations through additional equity and debt financings, and we may seek additional capital through arrangements with strategic partners or from other sources.

### **Collaboration Agreements**

We have entered into strategic collaborations for some of our therapeutic programs. As part of our business development strategy, we aim to increase the number of our research collaborations in order to derive further value from our platforms and more fully exploit their potential. Key terms of our current material collaborations are summarized below and more details are given under “Item 4. B. Business overview.”

#### ***Artiva***

In November 2022, we announced a collaboration with Artiva Biotherapeutics with the goal of advancing the development of the combination of AFM13 with Artiva’s AB-101 NK cell therapy into a potential registration enabling study. Affimed shall be responsible for all costs associated with the development of the combination therapy (including all clinical trial costs), except that Affimed and Artiva shall each bear 50% of the costs and expenses incurred in connection with the performance of any confirmatory clinical trial required by the FDA. Artiva shall be solely responsible for all costs incurred by Artiva for the supply of AB-101 and certain other products used in the clinical trials. In addition, under Collaboration Agreement, the parties have agreed to make payments to each other to achieve a proportion of 67%/33% (Affimed/Artiva) of revenues generated by both parties from commercial sales of each party’s product as part of the combination therapy.

#### ***Roivant***

On November 9, 2020, we announced that we entered into a license and strategic collaboration agreement with a subsidiary of Roivant Sciences Ltd. (“Roivant”) to develop and commercialize novel ICE<sup>®</sup> molecules, including AFM32, in oncology. Under the terms of the agreement, we received \$60 million in upfront consideration, comprised of \$40 million in cash and pre-paid R&D funding, and \$20 million of newly issued shares in Roivant Sciences Ltd. We are eligible to receive up to an additional \$2 billion in milestones over time upon achievement of specified development, regulatory and commercial milestones, as well as tiered royalties on net sales.

We recognized revenues of €22.7 million in 2022.

#### ***Genentech***

On August 24, 2018 we entered into a research collaboration and license agreement with Genentech, a member of the Roche Group, for the development and commercialization of certain product candidates that contain novel NK cell engager-based immunotherapeutics to treat multiple cancers. Under the terms of the agreement, in the fourth quarter of 2018 we received \$96 million in initial upfront payments and other funding and additional payments in 2019 for development milestones and a final target nomination.

We recognized revenues of €18.5 million in 2022.

### **Financial Operations Overview**

#### ***Revenue***

To date, our revenues have consisted principally of collaboration and service revenue.

*Collaboration revenue.* Collaboration revenue for year ended December 31, 2022 amounted to €41.2 million, with €18.5 million from the Genentech collaboration and €22.7 million from the Roivant collaboration. Collaboration revenue for year ended December 31, 2021 amounted to €39.3 million, with €21.6 million from the Genentech collaboration and €17.7 million from the Roivant collaboration.

*Service revenue.* Service revenue is primarily revenue from service contracts entered into by AbCheck, our wholly owned, independently operated antibody screening platform. We recognized €0.2 million and €1.1 million of third party service revenue in 2022 and 2021, respectively. Service revenue of AbCheck is derived from third party contracts as well as from the utilization of the entity by Affimed. The increase or decrease in the use of AbCheck's service capabilities by Affimed has an impact on AbCheck's ability to generate third party revenues.

In the future, the timing of our revenue may vary significantly from the receipt of the related cash flows, as the revenue from some upfront or initiation payments is deferred and recognized as revenue over the estimated service period, while other revenue is earned when received, such as milestone payments or service fees.

Our revenue has varied substantially, especially due to the impact of collaboration revenue received from Genentech and Roivant. The amount of future revenue is dependent on the services performed and milestones reached for our existing collaborations and on our ability to conclude new collaboration arrangements and the terms we are able to negotiate with our partners. As our project work for both Genentech and Roivant comes to a close, we expect that recognition of revenue related to the upfront payments from such collaborations will significantly decrease in 2023. We remain eligible for milestones under the collaboration, and the revenues associated with any such milestones will be recognized at the time they are achieved.

#### **Other Income**

Other income for years 2021 and 2022 primarily relates to government grants for research and development projects of €0.3 million in 2021 and €0.6 million in 2022 and research collaborations where costs are shared equally between both parties of €1.1 million in 2021 and €0.9 million in 2022.

#### **Research and Development Expenses**

Research and development expenses consist principally of:

- salaries for research and development staff and related expenses, including benefits;
- costs for production of preclinical compounds and drug substances by contract manufacturers;
- fees and other costs paid to contract research organizations in connection with additional preclinical testing and the performance of clinical trials;
- costs of related facilities, materials and equipment;
- costs associated with obtaining and maintaining patents and other intellectual property;
- amortization and depreciation of tangible and intangible fixed assets used to develop our product candidates; and
- expenses for share-based payments.

Based on our current budget we expect that our total research and development expenses in 2023 will increase as compared to 2022. Our research and development expenses primarily relate to the following key programs:



*AFM13.* The following is a summary of completed and ongoing research and development activities for AFM13:

- In January 2023, the U.S. Food and Drug Administration (“FDA”) issued a written response to our pre-investigational new drug (“IND”) meeting request for the AFM13 and Artiva Biotherapeutics, Inc. AB-101 co-administered combination therapy in relapsed/refractory Hodgkin lymphoma and the exploratory arm evaluating the combination in r/r CD30-positive peripheral T-cell lymphoma. Based on the written response, Affimed remains on track to submit an IND in the first half of 2023 and, subject to FDA clearance of the IND, to initiate a clinical study during 2023.
- In December 2022, we provided a data update from the ongoing phase 1/2 study of the Company’s lead innate cell engager (ICE<sup>®</sup>) AFM13 precomplexed with cord blood-derived natural killer (cbNK) cells in patients with CD30-positive relapsed or refractory (R/R) Hodgkin and Non-Hodgkin lymphomas. Key observations as of the cutoff date include:
  - 31 Hodgkin lymphoma patients treated at the recommended phase 2 dose (RP2D) showed an objective response rate (ORR) of 97% and a complete response (CR) rate of 77%. Three of four NHL patients treated at the recommended dose achieved an objective response, including one CR. 63% of patients treated at the RP2D with at least 6 months follow-up after initial infusion (n=24) remain in complete response for at least 6 months. The treatment continues to be well tolerated in the larger patient population, with minimal side effects beyond the expected myelosuppression from the preceding lymphodepleting chemotherapy. No instances of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft versus host disease were observed. There were 20 infusion-related reactions in 294 infusions (6.8%) of AFM13 alone and one infusion-related reaction in 99 infusions (1%) of the cbNK cells precomplexed with AFM13. No dose-limiting toxicities were encountered.
- In December 2022, we released topline data from our phase 2 REDIRECT study investigating AFM13 monotherapy in patients with advanced-stage R/R Peripheral T Cell Lymphoma. Primary efficacy measures include objective response rate of 32.4% and a CR rate of 10.2%. Key secondary and exploratory outcome measures include safety, durability of response, progression free survival (PFS) and overall survival (OS). The safety profile of AFM13 was well managed and consistent with previously reported data of prior and ongoing clinical studies with AFM13. Median DoR was 2.3 months, median PFS was 3.5 months and median OS was 13.8 months. Based on the compelling data seen in Hodgkin lymphoma for the combination of AFM13 with cord blood-derived NK cells in the AFM13-104 study, we believe that the combination with AB-101 has a higher probability to deliver increased anti-tumor activity and a more durable clinical benefit to address the unmet need in this patient population. Accordingly, we do not intend to pursue an accelerated approval for AFM13 monotherapy in PTCL and will focus investment on clinical development in the combination of AFM13 with Artiva’s AB-101 NK cell product.
- In November 2022, we announced a new strategic partnership with Artiva Biotherapeutics (“Artiva”) to jointly develop, manufacture, and commercialize a combination therapy of ICE<sup>®</sup> AFM13 and Artiva’s cord blood-derived, cryopreserved off-the-shelf allogeneic NK cell product candidate, AB-101. Under the terms of the agreement, Affimed and Artiva will pursue the development of the AFM13/AB-101 combination treatment in the United States on a co-exclusive basis. Affimed will lead regulatory activities through Phase 2 and any confirmatory studies. Affimed will be responsible for funding clinical study costs through Phase 2, while Artiva will be responsible for the costs of supplying AB-101 and IL-2 for such studies. The companies will share confirmatory study costs on a 50/50 basis. Both companies will retain commercialization and distribution rights and book sales for their respective products. Affimed will be responsible for promotional activities and expenses of the combination therapy. Pursuant to the agreement, revenues from the combination will be shared, with Affimed receiving 67% of the combination therapy revenue and Artiva receiving 33%.
- We anticipate that our research and development expenses in 2023 for AFM13 will increase compared to those for 2022 due to the continuation of the existing clinical studies and the initiation of a new clinical study, pre-clinical studies and the scale-up of the production of AFM13 for commercial purposes.

*AFM24.* AFM24, a tetravalent, bispecific epidermal growth factor receptor, and CD16A-binding innate cell engager. Affimed expects to report data from all three ongoing AFM24 studies at scientific conferences in Q2/Q3 2023.

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**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:** Enrollment was completed in the 480 mg dose escalation cohort of 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. AFM24-102 includes patients with non-small cell lung cancer (EGFR wildtype), gastric and gastroesophageal junction adenocarcinoma and pancreatic/hepatocellular/biliary tract cancer. The treatments continue to show a well managed safety profile. Dose escalation was completed during the first quarter of 2023 with a weekly AFM24 dose of 480 mg confirmed as the recommended phase 2 dose. The phase 2 expansion phase of the study was initiated in the first quarter of 2023.

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 was completed in the dose cohort of 480 mg AFM24 weekly, with no DLTs observed to date. 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.** AFM28 is designed to bind to CD123, an established target in myeloid malignancies. We chose CD123 as it is almost universally expressed on leukemic blasts and leukemic stem cells in patients with AML, both at diagnosis and at relapse, and independently of cytogenetic risk. AFM28 is being developed for the treatment of patients with acute myeloid leukemia. In June 2022, we submitted an IND to the FDA for AFM28. Following feedback from the FDA related to the design of the dose escalation study, we made a strategic decision to voluntarily withdraw the IND and to focus early clinical development of AFM28 in jurisdictions outside of the U.S. Clinical trial applications were cleared in Belgium, Denmark, France and Spain, and the Company initiated recruitment into a phase 1 clinical study in the first quarter of 2023.

*Other projects and infrastructure costs.* Our other research and development expenses relate to our Genentech, Roivant and Artiva collaborations, and early-stage development/discovery activities. We have allocated a material amount of our resources to such discovery activities. The expenses mainly consist of salaries, manufacturing costs for pre-clinical study material and pre-clinical studies. In addition, we incur a significant amount of costs associated with our research and development that are non-project specific, including intellectual property-related expenses, depreciation expenses and facility costs. Because these are less dependent on individual ongoing programs, they are not allocated to specific projects. We assume that other projects and infrastructure costs will decrease in 2023 due to decreased early-stage development/discovery activities.

Since January 1, 2012, we have cumulatively spent €415.9 million on research and development. In the years ended December 31, 2020, 2021 and 2022, we spent €50.0 million, €81.5 million and €98.8 million, respectively, on research and development; €19.1 million, €19.8 million and €15.1 million thereof on AFM13; €8.7 million, €20.0 million and €21.7 million thereof on AFM24 and €2.2 million, €6.5 million and €9.3 million on AFM28. Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials. Research and development expenses are expected to increase as we advance and broaden the clinical development of AFM13, AFM24, AFM28 and certain of our other product candidates and further advance the research and development of our preclinical product candidates. The successful development of our product candidates is highly uncertain. At this time we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any milestone and royalty payments thereunder.

A change in the outcome of any of these variables with respect to the development of AFM13, AFM24, AFM28 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development, if we experience significant delays in enrollment in any clinical trials or if we encounter difficulties in manufacturing our clinical supplies, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

### ***General and Administrative Expenses***

Our general and administrative expenses consist principally of:

- salaries for employees other than research and development staff, including benefits;
- business development expenses, including travel expenses;
- professional fees for auditors and other consulting expenses not related to research and development activities;
- professional fees for lawyers not related to the protection and maintenance of our intellectual property;
- cost of facilities, communication and office expenses;
- IT expenses;
- amortization and depreciation of tangible and intangible fixed assets not related to research and development activities; and
- expenses for share-based payments.

We expect that our general and administrative expenses in 2023 will be higher compared to the expenses in 2022, and will further increase in the future as our business expands. These increases will likely include costs of additional personnel, increase in infrastructure costs, additional legal fees, IT expenses, managing directors' and supervisory directors' liability insurance premiums. In addition, we may grant share-based compensation awards to key management personnel and other employees, which may further contribute to an increase in general and administrative expenses in 2023.

## Results of Operations

The numbers below have been derived from our audited consolidated financial statements for the years ended December 31, 2021 and 2022. The discussion below should be read along with these financial statements, and it is qualified in its entirety by reference to them.

A discussion of changes in our results of operations during the year ended December 31, 2021 compared to the year ended December 31, 2020 has been omitted from this Annual Report on Form 20-F, but may be found in "Item 5. Operating and Financial Review and Prospects" in our Annual Report on Form 20-F for the year ended December 31, 2021, filed with the SEC on March 31, 2022, which is available free of charge on the SECs website at [www.sec.gov](http://www.sec.gov) and on Affimed's investor relations website at <https://www.affimed.com/investors/sec-and-financial-reports/>.

### Comparison of the years ended December 31, 2021 and 2022

	Year ended December 31,	
	2021	2022
	(in € thousand)	
<b>Total Revenue</b>	<b>40,366</b>	<b>41,353</b>
Other income - net	1,310	1,417
Research and development expenses	(81,488)	(98,814)
General and administrative expenses	(24,218)	(32,075)
<b>Operating loss</b>	<b>(64,030)</b>	<b>(88,119)</b>
Finance income/(costs)-net	6,509	2,117
<b>Loss before tax</b>	<b>(57,521)</b>	<b>(86,002)</b>
Income taxes	(2)	(2)
<b>Loss for the period</b>	<b>(57,523)</b>	<b>(86,004)</b>
<b>Total comprehensive loss</b>	<b>(65,216)</b>	<b>(92,051)</b>
<b>Loss per common share in € per share</b>	<b>(0.48)</b>	<b>(0.60)</b>

#### Revenue

Revenue increased from €40.4 million for the year ended December 31, 2021 to €41.4 million for the year ended December 31, 2022. Revenue for the year ended December 31, 2022 largely consisted of revenue from the Genentech and Roivant collaborations. The increase in revenue in 2022 as compared to 2021 was primarily driven by an increase in revenues from the Roivant collaboration.

#### Research and development expenses

R&D Expenses by Project	Year ended December 31,		
	2021	2022	Change %
	(in € thousand)		
Project			
AFM13	19,800	15,130	(24)%
AFM24	19,957	21,687	9 %
AFM28	6,451	9,290	44 %
Other projects and infrastructure costs	29,388	42,356	44 %
Share-based payment expense	5,892	10,351	76 %
<b>Total</b>	<b>81,488</b>	<b>98,814</b>	<b>21 %</b>

Research and development expenses increased 21% from €81.5 million in the year ended December 31, 2021 to €98.8 million in the year ended December 31, 2022, due to higher expenses for AFM24, AFM28, other projects and infrastructure and share-based payment expense. The variances in project related expenses between the year ended December 31, 2021 and the corresponding period in 2022 are mainly due to the following projects:

*AFM13.* In the year ended December 31, 2022, expenses decreased 24% compared to the year ended December 31, 2021 primarily due to a milestone payment included in 2021 which has not reoccurred in 2022.

*AFM24.* In the year ended December 31, 2022, expenses increased 9% compared to the year ended December 31, 2021, primarily due to the enrollment of patients in our ongoing phase 1/2a clinical trials and manufacturing activities for clinical trial material required for the ongoing studies.

*AFM28.* In the year ended December 31, 2022, expenses increased 44% compared to the year ended December 31, 2021, primarily due to additional expenses related to preclinical development preparation of the filing of the IND application with the FDA and preparation of manufacturing activities.

*Other projects and infrastructure costs.* In the year ended December 31, 2022, expenses increased 44% compared to the year ended December 31, 2021, primarily due to higher expenses incurred in relation to our earlier stage programs, including our collaborations with Roivant, and discovery/early stage development activities and infrastructure costs.

*Share-based payment expenses.* In the year ended December 31, 2022, expenses increased 76% compared to the year ended December 31, 2021 due to an increase in headcount, as well as an increase in the underlying fair value of newly issued share options.

#### *General and administrative expenses*

General and administrative expenses increased 32% from €24.2 million in the year ended December 31, 2021 to €32.1 million in the year ended December 31, 2022. In 2022, general and administrative expenses were largely comprised of (i) personnel expenses of €15.2 million (2021: €10.7 million), which increased due to an increase in head count and share-based payment expense; (ii) legal, consulting and audit costs of €8.3 million (2021: €8.1 million) and insurance expenses of €3.5 million (2021: €2.6 million), mainly comprising D&O insurance.

#### *Finance income / (costs)-net*

We recognized finance net income for the year ended December 31, 2022 of €2.1 million compared to €6.5 million for the year ended December 31, 2021. The year ended December 31, 2022 was primarily affected by foreign exchange gains of €3.4 million primarily related to cash and cash equivalents denominated in U.S. dollars as a result of the strengthening of the U.S. dollar compared to the Euro during 2022. The year ended December 31, 2021 was primarily affected by foreign exchange gains of €7.6 million primarily related to assets denominated in U.S. dollars as a result of the weakening of the U.S. dollar compared to the Euro during 2021.

## **B. Liquidity and Capital Resources**

Since our inception, we have not generated any revenue from product sales and we have incurred significant operating losses. For the years ended December 31, 2021 and 2022 we incurred net losses of €57.5 million and €86.0 million, respectively. We have funded our operations to date with the proceeds principally from the sales of our common shares and payments from collaboration partners.

Our cash and cash equivalents as of December 31, 2022 consist primarily of bank balances. We expect to continue this investment philosophy, though we may in the future decide to invest our available liquidity in other financial instruments. Based on our current operating and budget assumptions, we believe that our existing liquidity will enable us to fund our operating expenses and capital expenditure requirements into 2025.

As part of our contractual obligations, we are also bound by certain operating lease obligations. Operating lease obligations consist of payments pursuant to non-cancellable operating lease agreements relating to our lease of office and laboratory space. The majority of this space will expire in 2023 and the remaining space (less than 10%) in 2025. We signed a new lease contract for offices and laboratories in 2021 and we are planning to move to a new facility in Mannheim, Germany, in approximately mid-2023. The contractual lease term is ten years including a cancellation option after five years with an expected start mid-2023. The terms provide for renewal options. We also lease office and laboratory space in the Czech Republic that is contracted until December 2025 with a period of notice of three months.

In January 2021, we issued and sold 19,166,667 common shares and generated net proceeds after underwriter discounts and commissions and other offering expenses of €88.7 million in the aggregate pursuant to an underwritten offering of our common shares.

In November 2020, the Company implemented a \$75 million ATM program. During 2021, we had issued approximately 4.4 million shares from this program, generating approximately €24.4 million in net proceeds.

In November 2021, we entered into a new \$100 million ATM program and, as of December 31, 2022, 0.2 million common shares had been sold under the new ATM program, generating net proceeds of €1.6 million.

In April 2022, we issued and sold 25,875,000 common shares and generated net proceeds after underwriter discounts and commissions and other offering expenses of €89.8 million in the aggregate pursuant to an underwritten offering of our shares.

## Cash Flows

### *Comparison of the years ended December 31, 2021 and 2022*

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2021 and 2022:

	Year ended December 31,	
	2021	2022
	(in € thousand)	
Net cash used in operating activities	(86,591)	(104,892)
Net cash (used)/generated from for investing activities	(3,850)	5,605
Net cash generated from financing activities	133,581	88,557
Net changes to cash and cash equivalents	43,140	(10,730)
Cash and cash equivalents at the beginning of the year	146,854	197,630
Exchange-rate related changes of cash and cash equivalents	7,636	3,386
<b>Cash and cash equivalents at the end of the year</b>	<b>197,630</b>	<b>190,286</b>

Net cash used in operating activities amounted to €86.6 million in the year ended December 31, 2021 whereas net cash used in operating activities amounted to €104.9 million in the year ended December 31, 2022. The increase is due to higher cash expenditure for research and development as well as general and administrative activities.

We used cash in investing activities of €3.9 million in the year ended December 31, 2021, compared to cash of €5.6 million generated in the year ended December 31, 2022. The investing activities in 2022 primarily relate to investments in laboratory equipment and leasehold improvements, and proceeds generated from the sale of the Roivant shares. The investing activities in 2021 primarily related to investments in intangible assets, laboratory equipment and leasehold improvements.

Net cash generated from financing activities in the year ended December 31, 2022 amounted to €88.6 million (2021: €133.6 million) and relate primarily to the net proceeds received from the public offering in 2022 of €89.8 million.



### **Material Cash Requirements**

Our short-term and long-term material cash requirements consist of operational and capital expenditures, some of which contain contractual obligations. Our primary uses of cash relate to clinical trial costs, third-party research and development services, the cost of manufacturing clinical trial material, manufacturing scale-up and validation costs, non-clinical development costs, personnel, laboratory and related supplies, milestone payments pursuant to certain of our collaboration agreements, legal, intellectual property and other regulatory expenses and general overhead costs. Because our product candidates are in various stages of clinical and pre-clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. In addition, our expenditures as reported in our financial statements may be expected to be variable due to that uncertainty. The most significant contractual obligations are the operating leases at our facilities in Heidelberg and our future facilities in Mannheim, Germany. Our future minimum lease payments as of December 31, 2022 totaled €0.4 million related to short-term lease liabilities, and €0.2 million related to long-term lease liabilities. In addition, we have entered into a new lease agreement for new offices and laboratories expected to start mid-2023. Expected payments include monthly rent of €141,000, a one-time payment of €1,170,000 for laboratory construction and a security deposit of €503,000. See Note 23, Other commitments and contingencies, in the Notes to the Financial Statements in this Annual Report on Form 20-F for additional information.

Based on our current operating and budget assumptions, we believe that our existing liquidity will enable us to fund our operating expenses and capital expenditure requirements into 2025. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaboration, licensing, and other arrangements that we have or may establish, including any required milestone and royalty payments thereunder.

To address our financing needs, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, the ownership interest of our shareholders will be diluted, and the terms of any such securities may include liquidation or other preferences that adversely affect the rights of holders of our common shares.

We do not have any off-balance sheet arrangements, as defined under the rules and regulations of the Securities and Exchange Commission.

### **Cash and Funding Sources**

Our cash and cash equivalents as of December 31, 2022 were €190.3 million. Funding sources generally comprise proceeds from the issuance of equity instruments, loans, payments from collaboration agreements and government grants.

In May 2020, we implemented a \$50 million at-the-market (ATM) program providing for the sale of shares over time, which resulted in the sale of in total 12.5 million common shares and generated net proceeds of €34.5 million in the aggregate. In November 2020, we entered into a new ATM program for an amount not to exceed \$75 million, and as of December 31, 2021 a further 12.3 million common shares were sold, generating net proceeds of €58.9 million in the aggregate. In November 2021, we entered into a new \$100 million ATM program as of December 31, 2021 a further 0.2 million common shares were sold, generating net proceeds of €1.6 million in the aggregate.

On January 8, 2021, we entered into a new loan agreement with SVB. The loan agreement provides us with a senior secured term loan facility (the "2021 SVB Credit Facility") for up to €25.0 million, of which €10.0 million was available at closing and drawn in February 2021, and €15.0 million of which is available in two additional tranches of €7.5 million each, subject to the satisfaction of certain milestones and conditions. In December 2021, we drew on the first additional tranche of the loan, for net proceeds of €7.4 million. The second additional tranche of €7.5 million expired undrawn at the end of 2022.

The interest rate on amounts borrowed under the 2021 SVB Credit Facility is calculated as the sum of (i) the European Central Bank Base Rate plus (ii) an applicable margin of 5.5%, with European Central Bank Base Rate deemed to equal zero percent if the European Central Bank Base Rate is less than zero percent. The 2021 SVB Credit Facility matures in November 2025 with an interest-only period through December 1, 2022, with amortized payments of principal and interest thereafter in equal monthly installments. Borrowings under the 2021 SVB Credit Facility are secured by a pledge of 100% of our shares in Affimed GmbH, all intercompany accounts receivables owed by our subsidiaries to us and a security assignment of essentially all our bank accounts, inventory, trade receivables and payment claims as specified in the loan agreement governing the facility.

On January 15, 2021, we closed the sale of 16,666,667 of our common shares at the public offering price of \$6.00 per share in an underwritten public offering. Concurrent with closing, the underwriters exercised an option to purchase over-allotment shares and we sold an additional 2,500,000 shares at a price of \$6.00 per share. We received approximately €88.7 million in net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses.

On April 18, 2022, we closed the sale of 22,500,000 of our common shares at the public offering price of \$4.00 per share in an underwritten public offering. Concurrent with closing, the underwriters exercised an option to purchase over-allotment shares and we sold an additional 3,375,000 shares at a price of \$4.00 per share. We received approximately €89.8 million in net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses.

## **Funding Requirements**

We expect that we will require additional funding to complete the development of our product candidates and to continue to advance the development of our other product candidates. In addition, we expect that we will require additional capital to commercialize our product candidates, including AFM13, AFM24 and AFM28. If we receive regulatory approval for AFM13, AFM24, AFM28 or other earlier programs, and if we choose not to grant any licenses to partners, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We also continue to incur substantial costs associated with operating as a public company. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are not able to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Based on our current operating and budget assumptions, we believe that our existing liquidity will enable us to fund our operating expenses and capital expenditure requirements into 2025. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;

- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaboration, licensing, and other arrangements that we have or may establish, including any required milestone and royalty payments thereunder.

To address our financing needs, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, the ownership interest of our shareholders will be diluted, and the terms of any such securities may include liquidation or other preferences that adversely affect the rights of holders of our common shares.

**For more information as to the risks associated with our future funding needs, see “Item 3. Key Information—D. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.”**

**C. Research and development, patents and licenses, etc.**

See “Item 4. Information on the Company—A. History and Development of the Company” and “Item 4. Information on the Company—B. Business Overview.”

**D. Trend information**

See “Item 5. Operating and Financial Review and Prospects.”

**E. Critical Judgments and Accounting Estimates**

Please refer to Note 3 (“Significant accounting policies - Critical judgements and accounting estimates”) of our consolidated financial statements.

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Directors and senior management

We have a two-tier board structure consisting of our supervisory board (*raad van commissarissen*) and a separate management board (*raad van bestuur*).

Our supervisory board supervises the policies of the management board and the general course of the affairs of our business. The supervisory board gives advice to the management board and is guided by the interests of the business when performing its duties. The management board is in charge of managing the Company under the supervision of the supervisory board. The management board provides the supervisory board with such necessary information as the supervisory board requires to perform its duties.

The following table presents our supervisory directors. Bernhard R.M. Ehmer was re-appointed by the general meeting of shareholders on June 25, 2019 and on June 22, 2022. Ulrich M. Grau was re-appointed by the general meeting of shareholders on June 19, 2018 and on June 15, 2021. Mathieu Simon was re-appointed by the general meeting of shareholders on June 15, 2021. Thomas Hecht was re-appointed by the general meeting of shareholders on August 4, 2020. Harry Welten and Annalisa Jenkins were appointed by the general meeting of shareholders on August 4, 2020. Uta Kemmerich-Keil was appointed by the general meeting of shareholders on June 15, 2021. Thomas Hecht is the chairman of our supervisory board. The term of each of our supervisory directors will terminate on the date of the annual general meeting of shareholders in the year indicated below.

<b>Name</b>	<b>Age</b>	<b>Term</b>
Thomas Hecht	71	2023
Bernhard R.M. Ehmer	68	2025
Ulrich M. Grau	74	2024
Annalisa Jenkins	57	2023
Mathieu Simon	66	2024
Harry Welten	57	2023
Uta Kemmerich-Keil	56	2024

The following is a brief summary of the business experience of our supervisory directors. Each director's tenure reflects their tenure on the board of our predecessor Affimed Therapeutics AG. Unless otherwise indicated, the current business address for each of our supervisory directors is Affimed N.V., c/o Affimed GmbH, Technologiepark, Im Neuenheimer Feld 582, 69120 Heidelberg, Germany.

**Thomas Hecht, Chairman.** Dr. Hecht has been the chairman of our supervisory board since 2014, and previously had been the chairman of the supervisory board of our German operating subsidiary since 2007. He is head of Hecht Healthcare Consulting in Küsnacht, Switzerland, a biopharmaceutical consulting company founded in 2002. Dr. Hecht also serves as Chairman of Aelix Therapeutics and of the Board of Orion Biotechnology and as Member of the Board of Directors of BiolInvent, Sweden. Previously, Dr. Hecht served as a director of Humabs BioMed AG until August 2017 and he served as chairman of the board of directors of Cell Medica Ltd. Until the beginning of June 2020, he served as chairman of the board of directors of Vaximm AG, until March 2015, he served as chairman of the supervisory council of SuppreMol GmbH and until June 2016, of Delenex AG. Dr. Hecht was previously Vice President Marketing at Amgen Europe. A seasoned manager and industry professional, he held various positions of increasing responsibility in clinical development, medical affairs and marketing at Amgen between 1989 and 2002. Prior to joining the biopharmaceutical industry, he was certified in internal medicine and served as Co-Head of the Program for Bone Marrow Transplantation at the University of Freiburg, Germany.

**Bernhard R.M. Ehmer, Director.** Dr. Ehmer has been a member of our supervisory board since 2016. In May 2022, he was elected the chair of the board of directors and a member of the audit committee of Biotest AG, where he had served as chairman of the board of management until April 2019. Furthermore, he has been on the Board of Directors at Achilles Therapeutics since May 2022. He also served as chairman of the board of directors at Symphogen A/S, Denmark until June 2020. Prior to this, he worked for the Imclone Group, a wholly owned subsidiary of Eli Lilly, as president of Imclone Systems Corporation in the United States and as managing director in Germany. In 2007/2008 he was CEO of Fresenius Biotech, Germany and before this, Dr. Ehmer headed the Business Area Oncology of Merck KGaA, Darmstadt and served as head of Global Clinical Operations at Merck. Between 1986 and 1998 he held various functions at Boehringer Mannheim in Germany, Italy and Singapore. Dr. Ehmer holds a degree in medicine and worked in the Department of Internal Medicine at the Academic Teaching Hospital of the University of Heidelberg.

**Ulrich M. Grau, Director.** Dr. Grau has been a member of our supervisory board since July 2015. Prior to that, he served as an advisor to the management board of our German operating subsidiary beginning in May 2013. He has over 30 years of experience in the biotechnology and pharmaceutical industries including in general management, business development, corporate strategy and the development of new products and technologies. Dr. Grau was Chief Operating Officer at Micromet from 2011 to 2012. Between 2006 and 2010, Dr. Grau was a founder, President and CEO of Lux Biosciences, Inc., a clinical stage ophthalmic company. Previously, Dr. Grau served as President of Research and Development at BASF Pharma/ Knoll where he directed a global R&D organization with a development pipeline which included Humira. The majority of his career was at Aventis Pharma (now Sanofi), where he last held the position of Senior Vice President of global late stage development. Sanofi's product Lantus for the treatment of type 2 and type 1 diabetes is based on his inventions made during his early years as a scientist with Hoechst AG. Dr. Grau received his Ph.D. in chemistry and biochemistry from the University of Stuttgart and spent three years as a post-doctoral fellow at Purdue University in the field of protein crystallography.

**Annalisa Jenkins, Director.** Dr. Jenkins has been a member of Affimed's supervisory board since August 2020. She is a life sciences thought leader with over 25 years of biopharmaceutical industry experience. She has consistently mentored leadership teams advancing programs from basic research through clinical development, regulatory approval, and healthcare systems globally. Dr. Jenkins graduated with a degree in medicine from St. Bartholomew's Hospital in the University of London and received her Fellowship from the Royal College of Physicians London. She trained in cardiovascular medicine and was a research fellow at Imperial College. Earlier in her career, Dr. Jenkins was a medical officer in the British Royal Navy during the Gulf Conflict, achieving the rank of Surgeon Lieutenant Commander. She also held senior leadership roles at Merck Serono and Bristol Myers-Squibb over a period of 15 years. Dr. Jenkins previously served as President and CEO of Dimension Therapeutics, a leading gene therapy company she took public on the NASDAQ and subsequently sold to Ultragenyx. Following her relocation back to the United Kingdom, she served in numerous roles spanning the public, private and charitable sectors, including Genomics England, The King's Fund, and British Heart Foundation and Chair of YouBelong, a leading mental health care charity. She is also a board member of several growing public and private companies, including Oncimmune, AVROBIO, COMPASS Pathways and Mereo Biopharma. Dr. Jenkins serves on a number of advisory boards and frequently speaks on leadership with purpose, social entrepreneurship, diversity and innovation.

**Mathieu Simon, Director.** Dr. Simon has been a member of Affimed's supervisory board since 2018. Dr. Simon is a senior strategic advisor at Mediobanca Group, Milan, Madrid, Paris, in the healthcare sector. He is chairman of the board at Idorsia Pharmaceuticals, as well as chairman of AILEEN's Pharma in Milan (Italy). Dr. Simon serves also as independent board member at Lysogene (France) and VAXIMA AG (Switzerland). Dr. Simon has served as Collectis' Executive Vice-President since 2012 and as Chief Operating Officer since 2013. Dr. Simon also served as Chief Executive Officer of a former subsidiary of Collectis. He has been instrumental to the development of Collectis and its CAR Allogenic T-Cell platform. He also served as Chief Executive Officer of Ectycell in 2012. He served as Chairman of the Board of Celleartis AB until 2014 before its acquisition by Takara Bio. Prior to joining Collectis, Dr. Simon was Managing Director, Head of Global Pharma at Pierre Fabre SA, the third largest French Pharma Company. Beginning in 1994, he served at Wyeth Pharmaceuticals in both general management roles (President Managing Director of Wyeth SPA) and senior corporate role in Philadelphia, United States (SVP / Head of International Marketing and Medical Affairs).

**Harry Welten, Director.** Mr. Welten has been a member of our supervisory Board since August 2020. He serves as chairman and member of the board of directors of several biotechnology companies in Switzerland, Germany and the USA. Previously, Mr. Welten served as a director of Kuros Biosciences A.G. until June 2018 and DMS Imaging SA (formerly ASIT Biotech SA) until May 2020. Over the last 20 years, Mr. Welten served as Chief Financial Officer of both public as well as venture capital financed biotech companies. Mr. Welten has served in senior roles at UBS in Switzerland and New York for the first 15 years of his career. Mr. Welten has degrees in Banking, Finance and Economics as well as an MBA (honours) from Columbia University, NY, USA.

**Uta Kemmerich-Keil, Director.** Mrs. Kemmerich-Keil was elected as a member of Affimed's Supervisory Board in June 2021 and has over 20 years of executive experience in the pharmaceutical and chemical industry. Most recently she headed up the personal healthcare international business of P&G and has over 19 years of experience from Merck KGaA, where she served, inter alia, as Chief Executive Officer of the global OTC- and global Allergy business, EVP Finance, Investor Relations and M&A. Mrs. Kemmerich-Keil is a board member of several public and privately held companies like Schott AG, Klosterfrau Zürich AG and Röchling S.E. She is a board member and member of the Audit Committee of Karo Healthcare AB, Biotest AG and Beiersdorf AG. In Biotest AG she leads the audit committee. She holds a M.Sc. (Economics) and a M.A (Roman Philology) from Freiburg University and a Licence from Nouvelle Sorbonne, Paris.

The following table lists the members of our current management board:

Name	Age	Position
Adi Hoess	61	Chief Executive Officer
Wolfgang Fischer	59	Chief Operating Officer
Denise Mueller	54	Chief Business Officer
Andreas Harstrick	61	Chief Medical Officer
Arndt Schottelius	56	Chief Scientific Officer
Angus Smith	40	Chief Financial Officer

The following is a brief summary of the business experience of the members of our management board. Unless otherwise indicated, the current business addresses for the members of our management board is Affimed N.V., c/o Affimed GmbH, Technologiepark, Im Neuenheimer Feld 582, 69120 Heidelberg, Germany.

**Adi Hoess, Chief Executive Officer.** Dr. Hoess joined us in October 2010 as Chief Commercial Officer and since September 2011 has served as our Chief Executive Officer. He has more than 20 years of professional experience with an extensive background in general management, business development, product commercialization, fund raising and M&A. Prior to joining us, Dr. Hoess was Chief Commercial Officer at Jerini AG and Chief Executive Officer of Jenowis AG. At Jerini AG he was responsible for business development, marketing and sales and the market introduction of Firazyr. He also played a major role in the sale of Jerini to Shire plc. Dr. Hoess began his professional career in 1993 at MorphoSys. Dr. Hoess received his Ph.D. in chemistry and biochemistry from the University of Munich in 1991 and an M.D. from the Technical University of Munich in 1997.



**Wolfgang Fischer, Chief Operating Officer.** Dr. Fischer joined us in 2017 from Sandoz Biopharmaceuticals (Novartis Group). He has 20 years of experience in research and drug development with a focus on oncology, immunology and pharmacology. At Sandoz he managed the development and registration of Sandoz' biosimilar pipeline assets since 2012 and served as Global Head of Program and Project Management since 2014. Prior to joining Sandoz, he held various positions of increasing responsibility within the Novartis Group since 2003, including Medical Director Oncology for Novartis Pharma Switzerland AG as well as Regional Medical Director Hematology (Emerging Growth Markets), where he was responsible for the Hematology Medical Affairs program and supported the launch of several products in various countries. Dr. Fischer holds a Ph.D. in Cancer Research from the Swiss Federal Institute of Technology (ETH), Zurich, Switzerland. Thereafter, he completed postdoctoral fellowships at the Swiss Institute of Experimental Cancer Research, Lausanne, Switzerland and at the Scripps Research Institute, Department of Immunology, La Jolla, CA, USA, followed by a state doctorate (Habilitation) in Pharmacology and Toxicology at the Medical School of the University of Würzburg in Germany in 2003.

**Denise Mueller, Chief Business Officer and Co-President Affimed Inc.** Ms. Mueller joined us in 2016 following a 17-year career at Wyeth and Pfizer Inc. She has held leadership roles in U.S. and global marketing including launch of new products and line extensions in-line and globally. Ms. Mueller has also held the position of Disease Area Lead for multiple therapeutic areas where she was responsible for disease area strategy, indication strategy for multiple assets, early commercial development and market shaping. In addition to broad and extensive commercial experience, Ms. Mueller led and managed two of Pfizer's largest alliances and was the business development lead for Pfizer's rare disease business unit. Prior to joining pharmaceuticals, Ms. Mueller worked in hospital management running Emergency Medicine, Critical Care, in-house Pediatrics and hospitalist programs. Ms. Mueller holds a B.A. in Mathematics from Virginia Polytechnic and State University.

**Andreas Harstrick, M.D., Chief Medical Officer.** Dr. Harstrick agreed to serve as our Chief Medical Officer, starting in March 2020. He brings 30 years of extensive experience in cancer drug development, including the successful designing of clinical trials leading to approval of antibody drugs (Erbix<sup>®</sup>; Cyramza<sup>®</sup>) and in-depth experience in setting-up and managing clinical oncology teams. Dr. Harstrick was Chief Medical Officer at Molecular Partners AG from 2015 to 2019, where he oversaw clinical activities, including expansion of the clinical team, and was a member of the Management Board. Between 2012 and 2014, Dr. Harstrick was Senior Vice President Medical Sciences at ImClone Systems, a wholly-owned subsidiary of Eli Lilly and Company, where he was also a member of the Lilly Oncology Program Review Board and the Lilly Oncology Business Unit Development Committee. Prior to joining ImClone in 2008, Dr. Harstrick was Senior Vice President Global Clinical Development Unit Oncology at Merck Serono until 2008. Dr. Harstrick is an oncologist by training. He spent his medical career at the University Hospital and Cancer Center Hannover, Germany; the Roswell Park Cancer Institute, Buffalo NY; as well as the West German Cancer Center, Essen, Germany. He earned his MD at Medical School Hannover, Germany, and in 1999 he became Associate Professor for Internal Medicine, University of Essen, Germany.

**Arndt Schottelius, M.D. Ph.D., Chief Scientific Officer.** Dr. Schottelius joined Affimed as Chief Scientific Officer in April 2020. He brings over 20 years of deep drug discovery and development experience in cancer and immunology with a strong track record in building therapeutic antibody pipelines and advancing drugs through development. Most recently, Dr. Schottelius was Executive Vice President and Head of Research & Development at Kymab Group Limited, where he was responsible for expanding the therapeutic antibody portfolio. Dr. Schottelius previously served as Chief Development Officer at MorphoSys AG, developing the portfolio of proprietary therapeutic antibody programs in cancer and immunology. He was instrumental in in-licensing tafasitamab (MOR208) and drove strategic direction and development of the MOR208 program into multiple phase 2 trials, which were the basis for a fast-to-market registration path. Prior to his role at MorphoSys, Dr. Schottelius was a Director and Medical Director, Immunology Development at Genentech Inc., where he directed early and late-stage development programs of therapeutic antibodies. Before joining Genentech, Dr. Schottelius held science and management positions in immunology research at Schering AG and Berlex Biosciences. Dr. Schottelius holds a PhD and MD degree from the Albert Ludwigs University of Freiburg and is a lecturer at Ludwig Maximilian University of Munich with a habilitation in Experimental Internal Medicine. He practiced medicine as a resident physician in gastroenterology at the Charité-Universitätsmedizin in Berlin, Germany, and completed a postdoctoral fellowship at the Lineberger Cancer Center, University of North Carolina at Chapel Hill. Dr. Schottelius is a Non-Executive Board Member of the Board of Directors of Gubra ApS.



**Angus Smith, Chief Financial Officer and Co-President Affimed Inc.** Mr. Smith joined Affimed in July 2020 as Chief Financial Officer. Previously, he was Chief Financial Officer at Rockwell Medical, Inc., a biopharmaceutical company developing and commercializing anemia therapies. He has broad biopharmaceutical industry experience including financial strategy, capital markets, business development and operations. Prior to Rockwell, Mr. Smith served as Senior Vice President, Chief Business Officer and Principal Financial Officer at Pernix Therapeutics, a specialty pharmaceutical company focused on the acquisition, development and commercialization of prescription drugs. Mr. Smith began his career in healthcare investment banking, having most recently served as Director in the Healthcare Investment Banking Group at Cantor Fitzgerald in New York, NY. During his nearly decade-long investment banking tenure, he focused on strategic and financial advice for life science and healthcare companies. He has worked on a substantial number of transactions across the healthcare sector with an aggregate transaction value of more than \$15 billion. Mr. Smith holds a Bachelor of Arts in Mathematical Economics from Colgate University in Hamilton, NY.

## **B. Compensation**

### **Management services agreements**

Our managing directors have entered into management services agreements with us. The management services agreements of Adi Hoess became effective upon the consummation of our initial public offering. The management services agreement of Wolfgang Fischer became effective upon his appointment by the general meeting of shareholders on June 20, 2017. The management service agreements for Angus Smith, Arndt Schottelius and Andreas Harstrick became effective upon their appointment by the general meeting of shareholders on August 4, 2020. These agreements comprise the following elements: fixed salary, bonus payments, earmarked pension and social security payments and share-based compensation components. In addition, these agreements provide for benefits upon a termination of service. Adi Hoess and Wolfgang Fischer were reappointed as managing directors by the general meeting of shareholders on August 4, 2020 until 2023, and in connection with their reappointments their respective management services agreements were prolonged until 2023.

### **Long-term incentive plans**

#### **Equity Incentive Plan 2014**

In conjunction with the closing of our initial public offering, we established the Affimed N.V. Equity Incentive Plan 2014 (“the 2014 Plan”) with the purpose of advancing the interests of our shareholders by enhancing our ability to attract, retain and motivate individuals who are expected to make important contributions to us. The maximum number of shares available for issuance under the 2014 Plan equals 7% of the total outstanding common shares on September 17, 2014, or approximately 1.7 million common shares. On January 1 of any calendar year thereafter (including January 1, 2023), an additional 5% of the total outstanding common shares on that date becomes available for issuance under the 2014 Plan. As of January 1, 2023, we had approximately 19.4 million common shares available for issuance, and approximately 18.1 million common shares subject to issuance under outstanding awards. The absolute number of shares available for issuance under the 2014 Plan will increase automatically upon the issuance of additional shares by the Company. The option exercise price for options under the 2014 Plan is the fair market value of a share as defined in the 2014 Plan on the relevant grant date. We are following home country rules relating to the re-pricing of stock options. Under applicable Dutch law, re-pricing is permissible, provided this falls within the framework set by the remuneration policy for the Management Board and the 2014 Plan.

*Plan administration.* The 2014 Plan is administered by our compensation committee. Approval of the compensation committee is required for all grants of awards under the 2014 Plan. The compensation committee may delegate to the managing directors the authority to grant equity awards under the 2014 Plan to our employees.

*Eligibility.* Supervisory directors, managing directors and other employees and consultants of the Company are eligible for awards under the 2014 Plan.

*Awards.* Awards include options and restricted stock units.

*Vesting period.* Subject to any additional vesting conditions that may be specified in an individual grant agreement, and the accelerated vesting conditions below, the plan provides for three year vesting of stock options. One-third of the stock options granted to participants in connection with the start of their employment vest on the first anniversary of the grant date, with the remainder vesting in equal tranches at the end of each 3-month period thereafter. Stock options granted to other participants vest in equal tranches at the end of each 3-month period after the grant date over the course of the vesting period. The compensation committee will establish a vesting schedule for awards granted to supervisory directors as well as for any awards in the form of restricted stock units.

*Accelerated vesting.* Unless otherwise specified in an individual grant agreement, the 2014 Plan provides that upon a change of control of the Company (as defined in the 2014 Plan) all then outstanding equity awards will vest and become immediately exercisable. It also provides that upon a participant's termination of service due to (i) retirement (or after reaching the statutory retirement age), (ii) permanent disability rendering the relevant participant incapable of continuing employment or (iii) death, all outstanding equity awards that would have vested during a 12-month period following such termination of service will vest and become immediately exercisable. Otherwise at termination all unvested awards will be forfeited. If a participant experiences a termination of service without "cause" or for "good reason" (in each case, as defined in the 2014 Plan) within six months prior to a change of control, the Company will make a cash payment equivalent to the economic value that the participant would have realized in connection with the change of control upon the exercise and sale of the equity awards that such participant forfeited upon his or her termination of service. In connection with a change of control and subject to the approval of the supervisory board, the management board may amend the exercise provisions of the 2014 Plan.

### Compensation of Managing Directors and Supervisory Directors

The compensation, including benefits in kind, accrued or paid to our managing directors and supervisory directors with respect to the year ended December 31, 2022, for services in all capacities is shown below on an individual basis. Further details for the compensation for our managing directors and supervisory directors are given in notes 19 and 24 to our consolidated financial statements as of and for the year ending December 31, 2022. As of December 31, 2022, we have no amounts set aside or accrued to provide pension, retirement or similar benefits to our managing directors and supervisory directors.

#### Director Compensation 2022

##### Managing Directors

(in € thousand)	Adi Hoess	Wolfgang Fischer	Andreas Harstrick	Denise Mueller	Arndt Schottelius	Angus Smith	Total
Periodically paid compensation	523	451	374	436	453	478	2,715
Bonuses	241	145	120	144	146	151	947
<b>Total cash compensation</b>	<b>764</b>	<b>596</b>	<b>494</b>	<b>580</b>	<b>599</b>	<b>629</b>	<b>3,662</b>
2014 Plan share-based payment expense	1,836	1,000	938	918	958	1,082	6,732
<b>Total share-based payment expense</b>	<b>1,836</b>	<b>1,000</b>	<b>938</b>	<b>918</b>	<b>958</b>	<b>1,082</b>	<b>6,732</b>

##### Supervisory directors

(in € thousand)	Thomas Hecht	Bernhard Ehmer	Ulrich Grau	Annalisa Jenkins	Mathieu Simon	Harry Welten	Uta Kemmerich-Keil	Total
Periodically paid compensation	115	52	58	53	50	49	54	431
<b>Total cash compensation</b>	<b>115</b>	<b>52</b>	<b>58</b>	<b>53</b>	<b>50</b>	<b>49</b>	<b>54</b>	<b>431</b>
2014 Plan share-based payment expense	247	164	164	192	164	192	247	1,370
<b>Total share-based payment expense</b>	<b>247</b>	<b>164</b>	<b>164</b>	<b>192</b>	<b>164</b>	<b>192</b>	<b>247</b>	<b>1,370</b>

## Stock options granted under the Equity Incentive Plan 2014

### Managing directors – share options with service conditions

<u>Beneficiary</u>	<u>Grant date</u>	<u>Number of options</u>	<u>Strike price USD</u>	<u>Expiration date</u>
Adi Hoess	March 18, 2022	400,000	4.46	March 18, 2032
Wolfgang Fischer	March 18, 2022	220,000	4.46	March 18, 2032
Andreas Harstrick	March 18, 2022	220,000	4.46	March 18, 2032
Denise Mueller	March 18, 2022	220,000	4.46	March 18, 2032
Arndt Schottelius	March 18, 2022	220,000	4.46	March 18, 2032
Angus Smith	March 18, 2022	220,000	4.46	March 18, 2032
<b>Total</b>		<b>1,500,000</b>		

These options vest in installments over three years and can be exercised up to 10 years after the grant date.

### Managing directors – share options with market conditions

<u>Beneficiary</u>	<u>Grant date</u>	<u>Number of options</u>	<u>Strike price USD</u>	<u>Expiration date</u>
Adi Hoess	March 30, 2022	325,000	4.45	March 30, 2024
Wolfgang Fischer	March 30, 2022	200,000	4.45	March 30, 2024
Andreas Harstrick	March 30, 2022	200,000	4.45	March 30, 2024
Denise Mueller	March 30, 2022	200,000	4.45	March 30, 2024
Arndt Schottelius	March 30, 2022	200,000	4.45	March 30, 2024
Angus Smith	March 30, 2022	200,000	4.45	March 30, 2024
<b>Total</b>		<b>1,325,000</b>		

These options consists of three tranches, one-third of the total grant will vest when the volume-weighted average share price over the preceding thirty trading days reaches \$12.00, \$15.00, and \$18.00, respectively. Except with respect to a change of control, these options shall not vest before the first anniversary of the grant date. The contractual lifetime of the options is two years. Any unvested awards on the date that is two years following the grant date will lapse.

### Supervisory directors

<u>Beneficiary</u>	<u>Grant date</u>	<u>Number of options</u>	<u>Strike price USD</u>	<u>Expiration date</u>
Thomas Hecht	March 18, 2022	45,000	4.46	March 18, 2032
Bernhard Ehmer	March 18, 2022	30,000	4.46	March 18, 2032
Ulrich M. Grau	March 18, 2022	30,000	4.46	March 18, 2032
Annalisa Jenkins	March 18, 2022	30,000	4.46	March 18, 2032
Mathieu Simon	March 18, 2022	30,000	4.46	March 18, 2032
Harry Welten	March 18, 2022	30,000	4.46	March 18, 2032
Uta Kemmerich-Keil	March 18, 2022	30,000	4.46	March 18, 2032
<b>Total</b>		<b>225,000</b>		

Dutch law provides that we must establish a policy in respect of the remuneration of our managing directors and supervisory directors. With respect to remuneration in the form of plans for shares or rights to shares (such as the Equity Incentive Plan 2014 mentioned above) the policy for managing directors must set out the maximum number of shares or rights to shares to be granted as well as the criteria for grants and for amending existing grants. The remuneration policies for the supervisory board and for the managing directors were adopted and approved by the general meeting on September 17, 2014 prior to the consummation of our initial public offering and have been amended subsequently, on August 4, 2020 and on June 22, 2022, each time with the approval of the general meeting. The remuneration policy for the supervisory board established the compensation for our supervisory directors. The remuneration policy for the managing directors provides the supervisory board with a framework within which the supervisory board determines the remuneration of the managing directors.

Our remuneration policy for our managing directors, which was last amended on June 22, 2022 with the approval of the general meeting, provides the supervisory board with the authority to enter into management services agreements with managing directors that provide for compensation consisting of base compensation, performance-related variable compensation, long-term equity incentive compensation (as detailed in the terms of the Equity Incentive Plan 2014 described above), pension and other benefits and severance pay and benefits. The remuneration policy for the managing directors provides that the annual cash bonus payable to managing directors may not exceed 100% of the annual base gross salary and will be based upon the achievement of set strategic, financial and operating goals for the period. Subject to the limitation set out in the preceding sentence, the supervisory board may decide, based on a proposal of the compensation, nomination and corporate governance committee which is justified by the financial results and performance of the Company, to increase the cash bonus payable to an individual managing director for any given year in case of exceptional achievements of that managing director, provided, that such increased bonus should not result in a significant discrepancy between the size of the bonus and the respective results and performance of the Company. In addition, the remuneration policy for managing directors allows for cash termination payments, which may not exceed 100% of the managing director's base salary, increased with the average variable compensation as referred to in (clause 4 of) the policy (the "STI Variable Compensation") over the last full three years, or if the term of office of the managing director is shorter than three years, the average received STI Variable Compensation over the shorter period. This policy also allows for additional compensation and benefits to our managing directors following a change of control. In the event of exceptional circumstances, the supervisory board, upon recommendation of the compensation, nomination and corporate governance committee, may decide to temporarily derogate from the remuneration policy for the managing directors. Such derogation for exceptional circumstances only covers situations in which the derogation is deemed necessary to serve the interests of the Company.

Our remuneration policy for the supervisory directors, which was last amended on June 22, 2022 with the approval of the general meeting, provides for cash compensation and initial and annual equity awards. This is permissible under Dutch law, but constitutes a deviation from the DCGC. The remuneration policy for our supervisory directors establishes that each supervisory director will be entitled to an annual retainer of €20,000, provided that the chairman of the supervisory board will be entitled to an annual retainer of €75,000. In addition, the chairmen of standing committees established by the supervisory board are each entitled to annual retainers of €15,000. Supervisory directors will also be paid €3,000 for each in-person supervisory board meeting and €1,500 for each virtual/telephonic supervisory board meeting, provided that the duration of such virtual/telephonic supervisory board meeting exceeds 30 minutes. The members of each committee will be paid €1,500 for each in-person committee meeting and €750 for each virtual/telephonic committee meeting, provided that the duration of such virtual/telephonic committee meeting exceeds 30 minutes. In addition, we will grant any newly elected member of the supervisory board an initial award of stock options to purchase 60,000 common shares. These initial stock options will vest over a three-year period, with 1/3<sup>rd</sup> vesting on the first anniversary of the grant date, and the remainder vesting in equal installments at the end of each three-month period following the first anniversary of the date of the grant. In addition, the remuneration policy provides that annually the company will grant the chairman of the supervisory board options to purchase 45,000 common shares, and each other supervisory director stock options to purchase 30,000 common shares (each such award referred to as an "Annual Award"). The grant date for the Annual Awards shall be determined by the supervisory board and must (i) be in the first quarter of the financial year and (ii) compliant with Affimed's insider trading policy. Annual Awards will be made to the supervisory board members under the condition that they will remain in office after the annual general meeting of that year. If, in any given year, a supervisory board member will no longer be in office after the annual general meeting, he or she will not receive an annual award for that year. Annual Awards vest in four quarterly instalments and are fully vested on the first anniversary of the date of grant. Initial awards and annual awards will be granted automatically on the grant date or dates as set forth in (section 4.1 of) the policy and as determined by the supervisory board pursuant to and in accordance with (section 4.2 of) the policy based on the approval by the shareholders of the remuneration policy and without any further decisions or approvals by the supervisory board or the company. Supervisory directors are also entitled to be reimbursed for their reasonable expenses incurred in attending meetings of the supervisory board and its committees.

## Insurance and Indemnification

Our managing directors and supervisory directors have the benefit of indemnification provisions in our Articles of Association. These provisions give managing directors and supervisory directors the right, to the fullest extent permitted by law, to recover from us amounts, including but not limited to litigation expenses, and any damages they are ordered to pay, in relation to acts or omissions in the performance of their duties. However, there is generally no entitlement to indemnification for acts or omissions that amount to willful (*opzettelijk*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct. In addition, upon consummation of our initial public offering, we entered into agreements with our managing directors and supervisory directors to indemnify them against expenses and liabilities to the fullest extent permitted by law. These agreements also provide, subject to certain exceptions, for indemnification for related expenses including, among others, attorneys' fees, judgments, penalties, fines and settlement amounts incurred by any of these individuals in any action or proceeding. In addition to such indemnification, we provide our managing directors and supervisory directors with directors' and officers' liability insurance.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to supervisory directors, managing directors or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## Diversity

Our supervisory board values diversity among its members. Our nominating and corporate governance committee, within the purview of its mandate, has the responsibility to take diversity into consideration as part of the overall director selection and nomination processes. The matrix below sets forth a summary of the diversity of our supervisory board as of March 15, 2023:

Supervisory Board Diversity Matrix (As of March 15, 2023)				
Country of Principal Executive Offices:	Germany			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	Yes for Demographic Background			
Total Number of Directors	7			
	Female	Male	Non-Binary	Did Not Disclose Gender
<b>Part I: Gender Identity</b>				
Directors	2	5	—	—
<b>Part II: Demographic Background</b>				
Underrepresented Individual in Home Country Jurisdiction	—			
LGBTQ+	—			
Did Not Disclose Demographic Background	—			

## C. Board practices

### Supervisory board

Our supervisory board supervises the policies of the management board and the general course of the affairs of our business. The supervisory board gives advice to the management board and is guided by our interests and our business when performing its duties. The management board provides the supervisory board with such necessary information as is required to perform its duties. Supervisory directors are appointed by the general meeting of shareholders upon a binding nomination of the supervisory board for a term of up to four years.

Our Articles of Association provide for a term of appointment of supervisory directors of up to four years. Furthermore, our Articles of Association state that a supervisory director may be reappointed, but that any supervisory director may be a supervisory director for no longer than twelve (12) years. Our supervisory directors are appointed for different terms as a result of which only approximately one third of our supervisory directors will be subject to election in any one year. Such an appointment has the effect of creating a staggered board and may deter a takeover attempt.

The supervisory board meets as often as a supervisory board member deems necessary. In a meeting of the supervisory board, each supervisory director has a right to cast one vote. All resolutions by the supervisory board are adopted by an absolute majority of the votes cast. In the event the votes are equally divided, the chairman has the decisive vote. A supervisory director may grant another supervisory director a written proxy to represent him at the meeting.

Our supervisory board can pass resolutions outside of meetings, provided that the resolution is adopted in writing and all supervisory directors have consented to adopting the resolution outside of a meeting.

Our supervisory directors do not have a retirement age requirement under our Articles of Association.

### **Management board**

The management board is in charge of managing us under the supervision of the supervisory board. The number of managing directors is determined by our supervisory board. Managing directors are appointed by the general meeting of shareholders upon a binding nomination of the supervisory board.

At least once per year the management board informs the supervisory board in writing of the main lines of our strategic policy, the general and financial risks and the management and control system.

We have a strong centralized management board led by Adi Hoess, our Chief Executive Officer, who has a strong track record in the development and commercialization of new medicines. Our management team has extensive experience in the biopharmaceutical industry, and key members of our team have played an important role in the development and commercialization of approved drugs.

### **Supervisory Board Committees**

#### **Audit committee**

The audit committee, which consists of Uta Kemmerich-Keil (Chairwoman), Harry Welten and Bernhard Ehmer, assists the board in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee is directly responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our supervisory board has determined that Uta Kemmerich-Keil, Harry Welten and Bernhard Ehmer satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. The supervisory board has determined that both Uta Kemmerich-Keil and Harry Welten qualify as an “audit committee financial expert,” as such term is defined in the rules of the SEC.

The audit committee is responsible for recommending the appointment of the independent auditor to the general meeting of shareholders; the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services; pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services; evaluating the independent auditor’s qualifications, performance and independence, and presenting its conclusions to the full supervisory board on at least an annual basis and reviewing and discussing with the management board and the independent auditor our annual audited financial statements and quarterly financial statements prior to the filing of the respective annual and quarterly reports, among other things.

The audit committee meets as often as one or more members of the audit committee deem necessary, but in any event at least four times per year. The audit committee meets at least once per year with our independent accountant, without our management board being present. The audit committee reviews information security matters no less than once per year.

#### **Compensation, nomination & corporate governance committee**

The Compensation, nomination and corporate governance committee, which consists of Ulrich Grau (Chairman), Bernhard Ehmer, Thomas Hecht and Mathieu Simon, assists the supervisory board *inter alia* in determining management board compensation. The committee recommends to the supervisory board for determination the compensation of each of our managing directors. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard supervisory director fees. As permitted by the listing requirements of Nasdaq, we have opted out of Nasdaq Listing Rule 5605(d) which requires that a compensation committee consist entirely of independent directors.



The Compensation, nomination and corporate governance committee is responsible for identifying, reviewing and approving corporate goals and objectives relevant to management board compensation; analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of the managing directors; evaluating each managing director's performance in light of such goals and objectives and determining each managing director's compensation based on such evaluation and determining any long-term incentive component of each managing director's compensation in line with the remuneration policy and reviewing our management board compensation and benefits policies generally, among other things.

The Compensation, nomination and corporate governance committee also assists our supervisory board in identifying individuals qualified to become members of our supervisory board consistent with criteria established by our supervisory board and in developing our corporate governance principles. In 2021, the Supervisory Board delegated the oversight of the Company's Compliance Management System to the Compensation, nomination and corporate governance committee. The Compensation, nomination and corporate governance committee is also responsible for the oversight of our information security management system, including the audit results of the information security certification and material information breaches and cybersecurity attacks and to monitor the development and implementation of our ESG strategy, including any goals with respect to ESG and sustainability matters. As permitted by the listing requirements of Nasdaq, we have opted out of Nasdaq Listing Rule 5605(e) which requires independent director oversight of director nominations.

#### **Strategic committee**

The strategic committee, which consists of Thomas Hecht (Chairman), Harry Welten, Mathieu Simon and Annalisa Jenkins, assists our supervisory board in discharging its supervisory, monitoring and advisory duties with respect to the development and implementation of the Company's overall strategy and the risks inherent to its business activities, as well as with respect to strategic initiatives identified by the Company from time to time.

#### **Research and development committee**

The research and development committee, which consists of Annalisa Jenkins (Chairwoman), Ulrich Grau and Mathieu Simon, assists our supervisory board in aligning the R&D strategy of the Company with the overall Company strategy, to evaluate critical junctures of research and development activities and assess the competitive landscape and the impact on the Company's strategy and business.

#### **D. Employees**

As of March 23, 2023, our total headcount is 228 (219 full time equivalents), approximately 70% of whom have an advanced academic degree (Diploma/ Master, PhD, MD).

None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

#### **E. Share ownership**

See "Item 7. Major Shareholders and Related Party Transactions—A. Major shareholders."

### **ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

#### **A. Major shareholders**

The following table presents information relating to the beneficial ownership of our common shares as of March 15, 2023, by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding common shares (as of the date of such stockholder's Schedule 13D or Schedule 13G filing for Affimed N.V. with the SEC);
- each of our managing directors and supervisory directors; and
- all managing directors and supervisory directors as a group.



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The number of common shares beneficially owned by each entity, person, managing director or supervisory director is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any common shares over which the individual has sole or shared voting power or investment power as well as any common shares that the individual has the right to acquire within 60 days of March 15, 2023 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person.

The percentage of shares beneficially owned is computed on the basis of 149,339,335 of our common shares outstanding as of March 15, 2023. Common shares that a person has the right to acquire within 60 days of March 15, 2023 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all managing directors and supervisory directors as a group. Each common share confers the right on the holder to cast one vote at the general meeting of shareholders and no shareholder has different voting rights. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Affimed N.V., c/o Affimed GmbH, Technologiepark, Im Neuenheimer Feld 582, 69120 Heidelberg, Germany.

Name and address of beneficial owner	Shares beneficially owned	
	Number	Percent (%)
Entities affiliated with Ridgeback Capital Management <sup>(1)</sup>	12,882,610	8.6
Entities affiliated with Ari Zweiman <sup>(2)</sup>	9,106,250	6.1
Entities affiliated with Blackrock, Inc. <sup>(3)</sup>	8,182,926	5.5
Entities affiliated with Cooperatieve Gilde Healthcare V U.A. <sup>(4)</sup>	8,125,000	5.4
<b>Managing Directors and Supervisory Directors</b>		
Adi Hoess <sup>(5)</sup>	2,535,925	1.7
Wolfgang Fischer	1,082,456	0.7
Andreas Harstrick	403,333	0.3
Arndt Schottelius	478,333	0.3
Angus Smith	524,169	0.3
Denise Mueller	541,674	0.4
Thomas Hecht	340,368	0.2
Bernhard R.M. Ehmer	178,333	0.1
Ulrich M. Grau	170,000	0.1
Annalisa Jenkins	120,000	0.1
Mathieu Simon	110,000	0.1
Harry Welten	110,000	0.1
Uta Kemmerich-Keil	60,000	0.0
<b>All managing directors and supervisory directors as a group (13 persons)</b>	<b>6,654,591</b>	<b>4.3</b>

(1) Represents shares beneficially owned by Ridgeback Capital Management LLC ("RCM"), Ridgeback Capital Investments LLC ("RCI") and Ridgeback Capital Investments L.P. ("RCILP"). Pursuant to an investment management agreement, RCM maintains investment and voting power with respect to the securities held or controlled by RCI. Mr. Wayne Holman controls RCM. RCI is the general partner of RCILP. This information is based on a statement filed on Schedule 13G with the SEC on February 14, 2023.

- (2) Represents shares beneficially owned by Mr. Ari Zweiman, 683 Capital Management, LLC and 683 Capital Partners, LP. Mr. Zweiman is the Managing Member of 683 Capital Management, LLC. 683 Capital Management, LLC is the investment manager of 683 Capital Partners, LP. This information is based on a statement filed on Schedule 13G with the SEC on February 14, 2023.
- (3) Represents shares beneficially owned by BlackRock, Inc and that were purchased by BlackRock Advisors, LLC, BlackRock Fund Advisors, BlackRock Asset Management Ireland Limited, BlackRock Institutional Trust Company, National Association, BlackRock Financial Management, Inc., BlackRock Investment Management, LLC, BlackRock Asset Management Canada Limited, BlackRock Investment Management (UK) Limited, BlackRock Japan Co., Ltd., all of which are subsidiaries of BlackRock, Inc. The address for BlackRock, Inc. is BlackRock, Inc., 55 East 52nd Street New York, NY 10055. This information is based on a statement filed on Schedule 13G with the SEC on February 3, 2023.
- (4) Represents shares beneficially owned by Cooperatieve Gilde Healthcare V U.A., Gilde Healthcare V Management B.V., Gilde Healthcare Holding B.V., Manapouri B.V. and Martemanshurk B.V. Gilde Healthcare V Management B.V. is the managing director of Cooperatieve Gilde Healthcare V U.A. and may be deemed to have voting, investment and dispositive power with respect to these securities. Gilde Healthcare V Management B.V. is fully owned by Gilde Healthcare Holding B.V., which is also its sole managing director. The managing directors of Gilde Healthcare Holding B.V. are Manapouri B.V. (of which Edwin de Graaf is the owner and managing director) and Martemanshurk B.V. (of which Pieter van der Meer is the owner and managing director). This information is based on a statement filed on Schedule 13G with the SEC on April 21, 2022.
- (5) Indicates that the director is entitled to receive common shares in connection with the carve-out plan described in Note 2 to our consolidated financial statements for the year ended December 31, 2016 pursuant to which 7.78% of the common shares of the Company outstanding immediately prior to the initial public offering owned by pre-IPO existing shareholders will be transferred to the beneficiaries upon the conditions set forth therein.

#### **Significant Changes in Ownership by Major Shareholders**

During 2020, we entered into two 'at-the-market' share sale agreements, which resulted in the sale of in total approximately 20.4 million common shares in 2020 and 4.4 million common shares in 2021 primarily to new investors.

On January 15, 2021, we completed a public offering and issued 19,166,667 common shares primarily to new investors.

In November 2021, we entered into an 'at-the-market' share sale agreement, which resulted in the sale of in total approximately 0.2 million common shares.

On April 18, 2022, we completed a public offering and issued 25,875,000 common shares primarily to new investors.

#### **Holders**

As of March 15, 2023, we had approximately six shareholders of record of our common shares; two of those shareholders of record are in the United States and hold a total of approximately 148.9 million common shares in the aggregate, or approximately 99.7% of our common shares. One of the U.S. shareholders of record is Cede and Company, a specialist United States financial institution that processes transfers of stock certificates on behalf of the Depository Trust Company, or DTC. Cede and Company therefore is the technical shareholder of record for nearly all of our issued shares held by DTC participants, as our shareholders do not themselves hold direct property rights in our common shares, but rather have contractual rights in such shares that are part of a chain of contractual rights involving Cede and Company.

#### **B. Related party transactions**

The following is a description of related party transactions we have entered into since January 1, 2022 with any of our members of our supervisory board or management board and the holders of more than 5% of our common shares.

## **Indemnification Agreements**

We have entered into indemnification agreements with our managing directors and supervisory directors. The indemnification agreements and our Articles of Association require us to indemnify our managing directors and supervisory directors to the fullest extent permitted by law. See “Item 6B. Compensation—Insurance and Indemnification” for a description of these indemnification agreements.

## **Other Agreements with Directors**

See “Item 6. Directors, Senior Management and Employees—B. Compensation” for a description of other agreements with our managing directors and supervisory directors.

## **C. Interests of Experts and Counsel**

Not applicable.

## **ITEM 8. FINANCIAL INFORMATION**

### **A. Consolidated statements and other financial information**

#### **Financial statements**

See “Item 18. Financial Statements,” which contains our financial statements prepared in accordance with IFRS.

#### **Legal Proceedings**

From time to time we are involved in legal proceedings that arise in the ordinary course of business. We believe that the outcome of these proceedings, if determined adversely, will not have a material adverse effect on our financial position. During the period covered by the audited and approved financial statements contained herein, we have not been a party to or paid any damages in connection with litigation that has had a material adverse effect on our financial position. Any future litigation may result in substantial costs and be a distraction to management and employer. No assurance can be given that future litigation will not have a material adverse effect on our financial position. For an additional discussion of certain risks associated with legal proceedings, see “Item 3. Key Information—D. Risk factors.”

#### **Dividends and Dividend Policy**

We have not declared cash dividends on our common shares in the years to 2020, 2021, or 2022. We currently expect to retain future earnings, if any, to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our supervisory board.

### **B. Significant changes**

A discussion of the significant changes in our business can be found under “Item 4. Information on the Company—A. History and development of the company.”

**ITEM 9. THE OFFER AND LISTING**

**A. Offering and listing details**

Not applicable.

**B. Plan of distribution**

Not applicable.

**C. Markets**

Our common shares began trading on the Nasdaq Global Market on September 12, 2014 under the symbol AFMD.

**D. Selling shareholders**

Not applicable.

**E. Dilution**

Not applicable.

**F. Expenses of the issue**

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

**A. Share capital**

Not applicable.

**B. Memorandum and articles of association**

Our shareholders adopted the Articles of Association filed as Exhibit 3.1 to our registration statement on Form F-1 (file no. 333-197097) with the SEC on September 17, 2014, and have subsequently adopted amendments to the Articles of Association, most recently on August 4, 2020.

**C. Material contracts**

Except as otherwise disclosed in this Annual Report on Form 20-F (including the Exhibits), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

**D. Exchange controls**

Cash dividends payable on our common shares and cash interest payments to holders of our debt securities may be remitted from the Netherlands to non-residents without legal restrictions imposed by the laws of the Netherlands, except that (i) such payments must be reported, if requested, to the Dutch Central Bank for statistical purposes only and (ii) the transfer of funds to jurisdictions subject to general economic sanctions adopted in connection with policies of the United Nations, European Commission or similar measures imposed directly by the Government of the Netherlands may be restricted.

## **E. Taxation**

The following summary contains a description of material German, Dutch and U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase common shares. The summary is based upon the tax laws of Germany, the Netherlands and the United States and regulations thereunder as of the date hereof, which are subject to change.

### **German Tax Considerations**

The following discussion is a summary of the material German tax considerations which—as the Company has its place of management in Germany and is therefore tax resident in Germany—relate to the purchase, ownership and disposition of our common shares both by a shareholder (an individual, a partnership or corporation) that has a tax domicile in Germany (that is, whose place of residence, habitual abode, registered office or place of management is in Germany) and by a shareholder without a tax domicile in Germany. This discussion does not cover the treatment of certain special companies such as those engaged in the financial and insurance sectors and pension funds. The information is not exhaustive and does not constitute a definitive explanation of all possible aspects of taxation that could be relevant for shareholders. The information is based on the tax law in force in Germany as of the date hereof (and its interpretation by administrative directives and courts) as well as typical provisions of double taxation treaties that Germany has concluded with other countries. Tax law can change—sometimes retrospectively. Moreover, it cannot be ruled out that the German tax authorities or courts may consider an alternative assessment to be correct that differs from the one described in this section.

This section cannot replace tailored tax advice to individual shareholders. They are therefore advised to consult their tax advisors regarding the tax implications of the acquisition, holding or transfer of shares and regarding the procedures to be followed to achieve a possible reimbursement of German withholding tax. Only such advisors are in a position to take the specific tax-relevant circumstances of individual shareholders into due account.

### **Income Tax Implications of the Purchase, Holding and Disposal of Shares**

In terms of the taxation of shareholders of the Company, a distinction must be made between taxation in connection with the holding of shares (“Taxation of Dividends”), taxation in connection with the sale of shares (“Taxation of Capital Gains”) and taxation in connection with the mortis causa or inter vivos (munificent) transfer of shares (“Inheritance and Gift Tax”).

#### ***Taxation of Dividends***

##### *Withholding tax*

As a general rule, the dividends distributed to the shareholder are subject to a withholding tax (*Kapitalertragsteuer*) of 25% and a solidarity surcharge of 5.5% thereon (i.e., 26.375% in total plus church tax, if applicable). The withholding tax is withheld and discharged for the account of the shareholders by the Company. Dividend payments that are funded from the Company’s contribution account for tax purposes (*steuerliches Einlagekonto*; § 27 Körperschaftsteuergesetz, German Corporation Income Tax Act) are generally not taxable in Germany and are not subject to withholding tax.

In general, the withholding tax must be withheld regardless of whether and to which extent the dividend is exempt from tax at the level of the shareholder and whether the shareholder is domiciled in Germany or abroad.

However, withholding tax on dividends distributed to a company domiciled in another EU Member State within the meaning of § 43b Einkommensteuergesetz, German Income Tax Act, in connection with Article 2 of Council Directive 2011/96/EU of November 30, 2011 on the common system of taxation applicable in the case of parent companies and subsidiaries of different member states, as amended (the "Parent-Subsidiary Directive") may be refunded or exempted upon application and subject to further conditions. This also applies to dividends distributed to a permanent establishment of such a parent company resident in another Member State of the European Union or to a parent company that is subject to unlimited tax liability in Germany, provided that the participation in the Company actually forms part of such permanent establishment's business assets. As further requirements for the refund or exemption of withholding tax under the Parent-Subsidiary Directive, the shareholder needs to hold—for corporate income tax purposes—at least a 10% direct stake in the company's registered capital for an uninterrupted period of at least 12 months and to file a respective application with the German Federal Central Tax Office (Bundeszentralamt für Steuern, Hauptdienstsz Bonn-Beuel, An der Kuppe 1, 53225 Bonn) using an official form. With the annual tax bill in 2019 the German legislator raised the threshold for the aforementioned exemption from trade tax for dividends for corporations within the meaning of Article 2 of the Parent-Subsidiary Directive to 15% for assessment periods beginning January 1, 2020.

If, in the case of such a holding by a company domiciled in another EU member state within the meaning of Article 2 of the Parent-Subsidiary Directive of at least 10%, shares held in collective custody (*girosammelverwahrt*) by the central securities depository (*Wertpapiersammelbank*) are treated as so-called "*abgesetzte Bestände*" (stock being held separately), the German tax authorities will not object when the main paying agent (*Hauptzahlstelle*) of the Company upon presentation of an exemption certificate (*Freistellungsbescheinigung*) and of a proof that this stock has been held separately, disburses the dividend without deducting withholding tax. An exemption certificate can be granted upon application (using official application forms) with the German Federal Central Tax Office (*Bundeszentralamt für Steuern*).

With respect to distributions made to other shareholders without a tax domicile in Germany, the withholding tax rate can be reduced in accordance with a double taxation treaty if Germany has entered into a double taxation treaty with the shareholder's state of residence and if the shares neither form part of the assets of a permanent establishment or a fixed place of business in Germany, nor form part of business assets for which a permanent representative in Germany has been appointed. Pursuant to most German tax treaties, including the income tax treaty between Germany and the United States, the German withholding tax rate is reduced to 15% (or, in certain cases, depending on the size of the shareholding, to a lower rate) with respect to distributions received by shareholders eligible for treaty benefits. The withholding tax reduction is generally granted by the German Federal Central Tax Office (*Bundeszentralamt für Steuern*) upon application in such a manner that the difference between the total amount withheld, including the solidarity surcharge, and the reduced withholding tax actually owed under the relevant double taxation treaty is refunded by the German Federal Central Tax Office.

Forms for the reimbursement and exemption from the withholding at source procedure are available at the German Federal Central Tax Office (<http://www.bzst.bund.de>) as well as at German embassies and consulates.

If dividends are distributed to corporations subject to limited tax liability, i.e., corporations with no registered office or place of management in Germany and if the shares neither belong to the assets of a permanent establishment or fixed place of business in Germany nor form part of business assets for which a permanent representative in Germany has been appointed, two-fifths of the tax withheld at the source can generally be refunded even if the prerequisites for a refund under the Parent-Subsidiary Directive or the relevant double taxation treaty are not fulfilled. The relevant application forms are available at the German Federal Central Tax Office (at the address specified above).

The exemption from withholding tax under the Parent-Subsidiary Directive as well as the aforementioned possibilities for a refund of withholding tax depend on certain other conditions being met (particularly the fulfillment of so-called substance requirements—*Substanzerfordernisse*).



In 2021, the German legislator adopted a reform of the withholding tax procedures by the Act to Modernize the Relief from Withholding Tax and the Certification of Capital Gains Tax (*Abzugsteuerentlastungs-modernisierungsgesetz*) which has been published in the German Federal Law Gazette on June 8, 2021. The reform comprises changes to the current withholding tax procedures in particular as regards the granting of exemption certificates (time limitation, conditions, etc.) and the application for refunds (in each case including allocation of competencies within tax authorities, procedural aspects and electronic reporting obligations by withholding agents) and as regards the application of German anti-directive/treaty shopping rules.

For shareholders resident in Germany (i.e., shareholders whose place of residence or usual place of abode or, in case of corporations, its statutory seat or place of management, is situated in Germany) holding their shares as business assets as well as for shareholders residing outside Germany (foreign shareholders) holding their shares in a permanent establishment or a fixed base in Germany, or as assets for which a permanent representative has been appointed in Germany, the tax withheld is credited against the shareholders' personal income tax or corporate income tax. Such crediting of withholding tax requires a certificate within the meaning of Section 45a (2) Income Tax Act.

Any tax withheld in excess of the shareholders' personal tax is refunded. The same principles apply to the solidarity surcharge.

For taxpayers who are subject to church tax, an automatic procedure for deducting church tax applies unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Central Tax Office. The church tax payable will be withheld together with the withholding tax. The taxpayer may refuse (block) the automatic query to the Federal Central Tax Office, which will then force an assessment by the taxpayer and the shareholder will be obliged to declare the dividends in his income tax return. The respective forms may be obtained from the German Federal Central Tax Office (*Bundeszentralamt für Steuern*), An der Kuppe 1, 53225 Bonn, Germany ([www.bzst.bund.de](http://www.bzst.bund.de)). If the church tax is withheld together with the withholding tax, the withholding tax will be reduced by 26.375% (including the solidarity surcharge) of the church tax levied on the withholding tax.

In case the shares are entrusted to a central securities depository (*Wertpapiersammelbank*) outside of Germany for custody as it is the case with the shares in the Company, the aforementioned withholding tax relief in accordance with applicable double taxation treaties as well as the credit of withholding tax described for shares held as private and as business assets is, pursuant to a special rule on the restriction of withholding tax credit, subject to the following three cumulative prerequisites: (i) the relevant shareholder must qualify as beneficial owner of the shares in the Company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the risk in value change related to the shares in the Company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder is not required to fully or largely, directly or indirectly, transfer the dividends to third parties. If these requirements are not met, then for a shareholder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply, if (i) the tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends or capital gains and (ii) the shareholder does not directly own 10% or more in the shares of the Company and is subject to income taxes in its state of residence, without being tax-exempt. In addition to the aforementioned restrictions, in particular, pursuant to a decree published by the German Federal Ministry of Finance dated July 17, 2017 (BMF, Schreiben vom 17.7.2017—IV C 1—S 2252/15/10030:05, DOK 2017/0614356), as amended (latest version dated July 9, 2021, docket: IV C 1—S 2252/19/10035:014, DOK 2021/0726914), the withholding tax credit may also be denied as an anti-abuse measure.

*Taxation of dividends of shareholders with a tax domicile in Germany Shares held as non-business assets*

Dividends distributed to shareholders with a tax domicile in Germany whose shares are held as non-business assets form part of their taxable capital investment income, which is subject to a flat tax at a rate of 25% plus solidarity surcharge of 5.5% thereon (i.e., 26.375% in total plus church tax, if applicable). The income tax owed for this dividend income is in general discharged by the withholding tax levied by the Company (flat tax—*Abgeltungsteuer*). Income-related expenses cannot be deducted from the capital investment income, except for an annual lump-sum deduction (*Sparer-Pauschbetrag*). The amount of the annual lump-sum deduction has been increased from €801 (€1,602 for married couples filing jointly) to €1,000 (€2,000 for married couples filing jointly) as of the assessment period 2023. However, the shareholder may request that his capital investment income (including dividends) along with his other taxable income is taxed at his individual progressive income tax rate (instead of the flat tax on capital investment income) if this results in a lower tax burden. In this case the withholding tax will be credited against the individual progressive income tax and any excess amount will be refunded. In this case as well income-related expenses cannot be deducted from the capital investment income, except for the aforementioned annual lump-sum deduction.

Exceptions from the flat tax apply upon application for shareholders who have a shareholding of at least 25% in the Company and for shareholders who have a shareholding of at least 1% in the Company and can take significant entrepreneurial influence on the Company's economic activity by a professional activity for the Company. In this case 60 % of the dividend income is taxed at the individual progressive income tax rate and 60% of the expenses in relation to the shareholding are deductible.

*Shares held as business assets*

Dividends from shares held as business assets by a shareholder with a tax domicile in Germany are not subject to the flat tax. The taxation depends on whether the shareholder is a corporation, a sole proprietor or a partnership (co-entrepreneurship). The withholding tax (including the solidarity surcharge thereon and church tax, if applicable) withheld and paid by the Company will be credited against the shareholder's income tax or corporate income tax liability (including the solidarity surcharge thereon and church tax, if applicable) or refunded in the amount of any excess.

*Corporations*

If the shareholder is a corporation with a tax domicile in Germany, the dividends are in general effectively 95% exempt from corporate income tax and the solidarity surcharge. Five percent of the dividends are treated as non-deductible business expenses and are therefore subject to corporate income tax (plus the solidarity surcharge thereon) at a total tax rate of 15.825%. In other respects, business expenses actually incurred in direct relation to the dividends may be deducted. However, dividends are not exempt from corporate income tax (including solidarity surcharge thereon), if the shareholder only held (or holds) a direct participation of less than 10% in the share capital of the distributing corporation at the beginning of the calendar year (hereinafter in all cases, a "Portfolio Participation" (*Streubesitzbeteiligung*)). Participations of at least 10% acquired during a calendar year are deemed to have been acquired at the beginning of the calendar year. Participations which a corporate shareholder holds through a partnership (including those that are co-entrepreneurships (*Mitunternehmenschaften*)) are attributable to the shareholder only on a *pro rata* basis at the ratio of the interest share of the shareholder in the assets of the relevant partnership. Shareholders affected by the rules for the taxation of dividends from Portfolio Participations are recommended to discuss the potential consequences with their tax advisors.

Dividends (after deducting business expenses economically related to the dividends) are subject to trade tax in the full amount, unless the participation amounts to at least 15% at the beginning of the relevant assessment period (trade tax participation exemption privilege). In this latter case, the dividends are not subject to trade tax; however, trade tax is levied on amounts considered to be non-deductible business expenses (amounting to 5% of the dividend). Trade tax ranges from 7% to approximately 18% depending on the municipal trade tax multiplier applied by the relevant municipal authority.

### *Sole proprietors*

If the shares are held as business assets by a sole proprietor with a tax domicile in Germany, only 60% of the dividends are subject to progressive income tax (plus the solidarity surcharge thereon) at a total tax rate of up to approximately 47.5% (plus church tax, if applicable), under the so-called partial income method (*Teileinkünfteverfahren*). Only 60% of the business expenses economically related to the dividends are tax-deductible. If the shares belong to a domestic permanent establishment in Germany of a business operation of the shareholder, the dividend income (after deducting business expenses economically related thereto) is fully subject to trade tax, unless the shareholder holds at least 15% of the share capital of the Company at the beginning of the relevant assessment period (trade tax participation exemption privilege). In this latter case the net amount of dividends, i.e., after deducting directly related expenses, is exempt from trade tax. As a rule, trade tax can be credited against the shareholder's personal income tax, either in full or in part, by means of a lump-sum tax credit method—depending on the level of the municipal trade tax multiplier and certain individual tax-relevant circumstances of the taxpayer.

### *Partnerships*

If the shareholder is a genuine business partnership or a deemed business partnership (co-entrepreneurship) with a permanent establishment in Germany, the income tax or corporate income tax is not levied at the level of the partnership but at the level of the respective partner. The taxation of every partner depends on whether the partner is a corporation or an individual. If the partner is a corporation, the dividends contained in the profit share of the partner will be taxed in accordance with the rules applicable for corporations (see "*Corporations*" above). If the partner is an individual, the taxation follows the rules described for sole proprietors, (see "*Sole proprietors*" above). Upon application and subject to further conditions, an individual as a partner can have his personal income tax rate reduced for earnings retained at the level of the partnership.

In addition, the dividends are generally subject to trade tax in the full amount at the partnership level if the shares are attributed to a German permanent establishment of the partnership. If a partner of the partnership is an individual, the portion of the trade tax paid by the partnership pertaining to his profit share will generally be credited, either in full or in part, against his personal income tax by means of a lump-sum method—depending on the level of the municipal trade tax multiplier and certain individual tax-relevant circumstances of the taxpayer. Due to a lack of case law and administrative guidance, it is currently unclear how the rules for the taxation of dividends from Portfolio Participations (see "*Corporations*" above) might impact the trade tax treatment at the level of the partnership. Shareholders are strongly recommended to consult their tax advisors. Under a literal reading of the law, if the partnership qualifies for the trade tax exemption privilege at the beginning of the relevant assessment period, the dividends should generally not be subject to trade tax. However, in this case, trade tax should be levied on 5% of the dividends to the extent they are attributable to the profit share of such corporate partners to whom at least 10% of the shares in the Company are attributable on a look-through basis, since such portion of the dividends should be deemed to be non-deductible business expenses. The remaining portion of the dividend income attributable to other than such specific corporate partners (which includes individual partners and should, under a literal reading of the law, also include corporate partners to whom, on a look-through basis, only Portfolio Participations are attributable) should (after the deduction of business expenses economically related thereto) not be subject to trade tax. Due to a lack of case law and administrative guidance, it is currently unclear how the rules for the taxation of dividends from Portfolio Participations (see "*Corporations*" above) might impact the trade tax treatment at the level of the partnership. Shareholders are strongly recommended to consult their tax advisors.

As of the assessment period 2022, partnerships may opt for taxation as corporations under certain conditions. Shareholders are advised to consult their individual tax advisor in this respect.

*Taxation of dividends of shareholders without a tax domicile in Germany*

Shareholders without a tax domicile in Germany whose shares are attributable to a German permanent establishment or fixed place of business or are part of business assets for which a permanent representative in Germany has been appointed, are also subject to tax in Germany on their dividend income. In this respect the provisions outlined above for shareholders with a tax domicile in Germany whose shares are held as business assets apply accordingly (“—*Taxation of dividends of shareholders with a tax domicile in Germany—Shares held as business assets*”). The withholding tax (including the solidarity surcharge thereon) withheld and passed on will be credited against the income or corporate income tax liability or refunded in the amount of any excess.

In all other cases, any German limited tax liability on dividends is discharged by withholding tax imposed by the Company. Withholding tax is only reimbursed in the cases and to the extent described above under “—*Withholding tax*”.

**Taxation of Capital Gains**

*Taxation of capital gains of shareholders with a tax domicile in Germany*

*Shares held as non-business assets*

Gains from the disposal of shares acquired after December 31, 2008 by a shareholder with a tax domicile in Germany and held as non-business assets are generally—regardless of the holding period—subject to a flat tax on capital investment income at a rate of 25% (plus the solidarity surcharge of 5.5% thereon, i.e., 26.375% in total plus church tax, if applicable).

The taxable capital gain is computed as the difference between (a) the sale proceeds and (b) the acquisition costs of the shares and the expenses related directly and economically to the disposal.

Only an annual lump-sum deduction of € 1,000 (€2,000 for married couples filing jointly) may be deducted from the entire capital investments income. It is not possible to deduct income-related expenses in connection with capital gains, except for the expenses directly related in substance to the disposal which can be deducted when calculating the capital gains. Losses from disposals of shares may only be offset against capital gains from the disposal of the shares or shares in other stock corporations during the same calendar year. Offsetting of overall losses with other income (such as business or rental income) and other capital income is not possible. Such losses are to be carried forward and to be offset against positive capital gains deriving from the sale of shares in stock corporations in future years. In case of a derecognition (*Ausbuchung*) or transfer of worthless shares (or other capital assets), the utilization of such loss is further restricted and can only be offset up to the amount of €20,000 per calendar year.

If the disposal of the shares is executed by a domestic credit institution, or domestic financial services institution (*inländisches Kredit-oder Finanzdienstleistungsinstitut*) (including domestic branches of foreign credit and financial services institutions), domestic securities trading company (*inländisches Wertpapierhandels-unternehmen*) or a domestic securities trading bank (*inländische Wertpapierhandelsbank*), and such office pays out or credits the capital gains (a “Domestic Paying Agent”), the tax on the capital gains will in general be discharged for the account of the seller by the Domestic Paying Agent imposing the withholding tax on investment income at the rate of 26.375% (including the solidarity surcharge thereon plus church tax, if applicable) on the capital gain.

However, the shareholder can apply for his total capital investment income together with his other taxable income to be subject to his progressive income tax rate, as opposed to the flat tax on investment income, if this results in a lower tax liability. In this case the withholding tax is credited against the individual progressive income tax and any resulting excess amount will be refunded. In this case as well income-related expenses cannot be deducted from the capital investment income, except for the aforementioned annual lump-sum deduction. Further, the limitations on offsetting losses are also applicable under the income tax assessment.

If the withholding tax or, if applicable, the church tax on capital gains, is not withheld by a Domestic Paying Agent, the shareholder is required to declare the capital gains in his income tax return. The income tax and any applicable church tax on the capital gains will then be collected by way of assessment.

Regardless of the holding period and the time of acquisition, gains from the disposal of shares are not subject to the flat tax but to individual progressive income tax if a shareholder domiciled in Germany, or, in the event of a munificent transfer, their legal predecessor, or, if the shares have been munificently transferred several times in succession, one of his legal predecessors at any point during the five years preceding the disposal directly or indirectly held at least 1% of the share capital of the Company (a “Qualified Holding”). In this case the partial income method applies to gains from the disposal of shares, which means that only 60% of the capital gains are subject to tax and only 60% of the losses on the disposal and expenses economically related thereto are tax deductible. Even though withholding tax has to be withheld by a Domestic Paying Agent in the case of a Qualified Holding, this does not discharge the tax liability of the shareholder. Consequently, a shareholder must declare his capital gains in his income tax return. The withholding tax (including the solidarity surcharge thereon and church tax, if applicable) levied and paid will be credited against the shareholder’s income tax liability as assessed (including the solidarity surcharge thereon and any church tax, if applicable) or refunded in the amount of any excess.

#### *Shares held as business assets*

Gains from the sale of shares held as business assets of a shareholder with a tax domicile in Germany are not subject to the flat tax. The taxation of the capital gains depends on whether the shareholder is a corporation, a sole proprietor or a partnership (co-entrepreneurship).

#### *Corporations*

If the shareholder is a corporation with a tax domicile in Germany, the gains from the disposal of shares are in general effectively 95% exempt from corporate income tax (including the solidarity surcharge thereon) and trade tax, regardless of the size of the participation and the holding period, and 5% of the gains are treated as non-deductible business expenses and are therefore subject to corporate income tax (plus the solidarity surcharge thereon) at a rate of 15.825% and trade tax (at a rate depending on the municipal trade tax multiplier applied by the municipal authority, generally between 7% and approximately 18%). As a rule, capital losses and other profit reductions in connection with shares (e.g., from a write-down) cannot be deducted for tax purposes. Currently, there are no specific rules for the taxation of gains arising from the disposal of Portfolio Participations.

#### *Sole proprietors*

If the shares are held as business assets by a sole proprietor with a tax domicile in Germany, only 60% of the gains from the disposal of the shares are subject to progressive income tax (plus the solidarity surcharge thereon) at a total tax rate of up to approximately 47.5%, and, if applicable, church tax (partial-income method). Only 60% of the losses on the disposal and expenses economically related thereto are tax deductible. If the shares belong to a German permanent establishment of a business operation of the sole proprietor, 60% of the gains of the disposal of the shares are, in addition, subject to trade tax.

Trade tax can be credited against the shareholder’s personal income tax liability, either in full or in part, by means of a lump-sum tax credit method—depending on the level of the municipal trade tax multiplier and certain individual tax-relevant circumstances of the taxpayer.

#### *Partnerships*

If the shareholder is a genuine business partnership or a deemed business partnership (co-entrepreneurship) with a permanent establishment in Germany, the income or corporate income tax is not levied at the level of the partnership but at the level of the respective partner. The taxation depends on whether the partner is a corporation or an individual. If the partner is a corporation, the capital gains from the shares as contained in the profit share of the partner will be taxed in accordance with the rules applicable to corporations (see “*Corporations*” above). For capital gains in the profit share of a partner that is an individual, the principles outlined above for sole proprietors apply accordingly (partial-income method, see above under “*Sole proprietors*”). Upon application and subject to further conditions, a partner that is an individual can obtain a reduction of his personal income tax rate for earnings retained at the level of the partnership.

In addition, capital gains from the shares are subject to trade tax at the level of the partnership if the shares are attributed to a domestic permanent establishment of a business operation of the partnership generally, (i) at 60% as far as they are attributable to the profit share of an individual partner, and (ii) currently, at 5% as far as they are attributable to the profit share of a corporate partner. Capital losses and other profit reductions in connection with the shares are currently not deductible for trade tax purposes if they are attributable to the profit share of a corporation; however, 60% of the capital losses are deductible, subject to general limitations, to the extent such losses are attributable to the profit share of an individual.

If the partner is an individual, the portion of the trade tax paid by the partnership attributable to his profit share will generally be credited, either in full or in part, against his personal income tax by means of a lump-sum method—depending on the level of the municipal trade tax multiplier and certain individual tax-relevant circumstances of the taxpayer.

As of the assessment period 2022, partnerships may opt for taxation as corporations under certain conditions. Shareholders are advised to consult their individual tax advisor in this respect.

#### *Withholding tax*

In case of a Domestic Paying Agent, the capital gains from shares held as business assets are in general subject to withholding tax in the same way as shares held as non-business assets by a shareholder (see “—*Taxation of capital gains of shareholders with a tax domicile in Germany—Shares held as non-business assets*”). However, the Domestic Paying Agent will not levy the withholding tax, provided that (i) the shareholder is a corporation, association of persons or estate with a tax domicile in Germany, or (ii) the shares belong to the domestic business assets of a shareholder, and the shareholder declares so to the Domestic Paying Agent using the designated official form and certain other requirements are met. If withholding tax is imposed by a Domestic Paying Agent, the withholding tax (including the solidarity surcharge thereon and church tax, if applicable) imposed and discharged will be credited against the income tax or corporate income tax liability (including the solidarity surcharge thereon and church tax, if applicable) or will be refunded in the amount of any excess.

#### *Taxation of capital gains of shareholders without a tax domicile in Germany*

Capital gains derived by shareholders not tax resident in Germany are only subject to German tax if the shareholder has a Qualified Holding in the Company or the shares belong to a domestic permanent establishment or fixed place of business or are part of business assets for which a permanent representative in Germany has been appointed.

In case of a Qualified Holding (as defined in “*Taxation of capital gains of shareholders with a tax domicile in Germany—Shares held as non-business assets*”), only 60% of the gains from the disposal of the shares are subject to progressive income tax plus the solidarity surcharge thereon (partial-income method), if the shareholder is a private individual. If the shareholder is a corporation and the shares do not belong to a domestic permanent establishment or fixed place of business and are not part of business assets for which a permanent representative in Germany has been appointed, the gains from the disposal of the shares should, according to a judgement of the German Federal Fiscal Court of 31 May 2017, I R 37/15, not be subject to corporate income tax; the legal fiction according to which 5% of the gains are treated as non-deductible business expenses shall not apply. The judgment seems to be accepted by tax authorities. Furthermore, most double taxation treaties provide for exemption from German taxation and attribute the right of taxation to the shareholder’s state of residence. According to the tax authorities there is no obligation to levy withholding tax at source in the case of a Qualified Holding if the shareholder submits to the Domestic Paying Agent a certificate of residence issued by a competent foreign tax authority.

With regard to capital gains or losses from shares attributable to a domestic permanent establishment or fixed place of business or which form part of business assets for which a permanent representative in Germany has been appointed, the above-mentioned provisions pertaining to shareholders with a tax domicile in Germany whose shares are business assets apply mutatis mutandis (see “*Taxation of capital gains of shareholders with a tax domicile in Germany—Shares held as business assets*”). The Domestic Paying Agent can refrain from deducting the withholding tax if the shareholder declares to the Domestic Paying Agent on an official form that the shares form part of domestic business assets and certain other requirements are met.



## **Abolishment of Solidarity Surcharge**

According to a bill enacted in December 2019, the solidarity surcharge has been partially abolished as of the assessment period 2021 for certain individual shareholders. The German law rules governing the solidarity surcharge are subject to court proceedings before the *Bundesfinanzhof* (German Federal Fiscal Court) and may become subject to judicial proceedings before the *Bundesverfassungsgericht* (German Supreme Court) for an examination of their constitutionality.

## **Inheritance and Gift Tax**

The transfer of shares to another person *mortis causa* or by way of munificent donation is generally subject to German inheritance or gift tax if:

- (i) the place of residence, habitual abode, place of management or registered office of the decedent, the donor, the heir, the donee or another acquirer is, at the time of the asset transfer, in Germany, or such person, as a German national, has not spent more than five continuous years outside of Germany without maintaining a place of residence in Germany, or
- (ii) the decedent's or donor's shares belonged to business assets for which there had been a permanent establishment in Germany or a permanent representative had been appointed, or
- (iii) the decedent or the donor, at the time of the succession or gift, held a direct or indirect interest of at least 10% of the Company's share capital either alone or jointly with other related parties.

The small number of double taxation treaties in respect of inheritance and gift tax which Germany has concluded to date usually provide for German inheritance or gift tax only to be levied in the cases under (i) and, subject to certain restrictions, in the cases under (ii). Special provisions apply to certain German nationals living outside of Germany and to former German nationals.

## **Other Taxes**

No German financial transfer taxes, VAT, stamp duties or similar taxes are currently levied on the purchase or disposal or other forms of transfer of the shares. However, for VAT purposes, an entrepreneur may opt for taxation in relation to disposals of shares, which are in principle exempt from value-added-tax, if the sale is made to another entrepreneur for the entrepreneur's business. Wealth tax is currently not levied in Germany.

However, on February 14, 2013, the European Commission published a proposal for a Directive for a common financial transaction tax in Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia. Until now, the Commission's proposal failed due to the opposition from certain EU member states, however, it may still be pursued in the future, thus it is unclear if and to what extent it will be implemented, if ever. The implementation of a financial transaction tax in Germany is no longer included in the most recent coalition agreement signed on December 7, 2021. Prospective holders are advised to seek their own professional advice in relation to the Commission's proposal to introduce a financial transaction tax.

## **Dutch Tax Considerations**

This "Dutch Tax Considerations" section outlines the principal Dutch tax consequences of the acquisition, holding, settlement, redemption and disposal of common shares in the capital of the Company, or the Shares. It does not present a comprehensive or complete description of all aspects of Dutch tax law which could be relevant to a holder of Shares (a "Shareholder"). For Dutch tax purposes, a Shareholder may include an individual or entity not holding the legal title to the Shares, but to whom, or to which, the Shares are, or the income from the Shares is, nevertheless attributed based either on this individual or entity owning a beneficial interest in the Shares or on specific statutory provisions. These include statutory provisions attributing Shares to an individual who is, or who has directly or indirectly inherited from a person who was, the settlor, grantor or similar originator of a trust, foundation or similar entity that holds the Shares.



This “Dutch Tax Considerations” section is intended as general information only. A prospective Shareholder should consult his own tax adviser regarding the tax consequences of any acquisition, holding or disposal of Shares.

This “Dutch Tax Considerations” section is based on Dutch tax law as applied and interpreted by Dutch tax courts and as published and in effect on the date of this Annual Report, including the tax rates applicable on that date, without prejudice to any amendments introduced at a later date and implemented with or without retroactive effect. This section does therefore not take into account the amendments to the Withholding Tax Act 2021 introducing an additional conditional Dutch withholding tax for dividend distributions to low-tax jurisdictions and in abusive situations (*Wet invoering conditionele bronbelasting op dividenden*), as these amendments are not yet in effect as of the date of this Form 20-F. Once these amendments become effective on January 1, 2024, dividends paid to certain entities considered related to the Company may be subject to an additional Dutch withholding tax equal to the highest corporate income tax rate at the time of the dividend payment. An entity is related if (i) it holds, directly or indirectly, a qualifying interest in the Company, (ii) the Company directly or indirectly holds a qualifying interest in the entity or (iii) an entity in which a third party holds a direct or indirect qualifying interest that also holds a qualifying interest in the Company. An entity is also considered related to the Company if the entity is part of a collaborating group (*samenwerkende groep*) of entities that jointly directly or indirectly holds a qualifying interest in the Company. The term “qualifying interest” means a direct or indirectly held interest - either by an entity individually or jointly if an entity is part of a collaborating group (*samenwerkende groep*) - that enables such entity or such collaborating group to exercise a definite influence over another entities’ decisions, such as the Company, and allows it to determine the other entities’ activities.

Any reference in this “Dutch Tax Considerations” section made to Dutch taxes, Dutch tax or Dutch tax law should be construed as a reference to any taxes of any nature levied by or on behalf of the Netherlands or any of its subdivisions or taxing authorities or to the law governing such taxes, respectively. The Netherlands means the part of the Kingdom of the Netherlands located in Europe.

Any reference made to a treaty for the avoidance of double taxation concluded by the Netherlands includes the Tax Regulation for the Kingdom of the Netherlands (*Belastingregeling voor het Koninkrijk*), the Tax Regulation for the State of the Netherlands (*Belastingregeling voor het land Nederland*), the Tax Regulations for the Netherlands and Curacao (*Belastingregeling Nederland Curacao*), the Tax Regulations for the Netherlands and St. Maarten (*Belastingregeling Nederland Sint Maarten*) and the Agreement between the Taipei Representative Office in the Netherlands and the Netherlands Trade and Investment Office in Taipei for the avoidance of double taxation.

This “Dutch Tax Considerations” section does not describe any Dutch tax considerations or consequences that may be relevant where a Shareholder:

- (i) is an individual and the Shareholder’s income or capital gains derived from the Shares are attributable to employment activities, the income from which is taxable in the Netherlands;
- (ii) has a substantial interest (*aanmerkelijk belang*) or a fictitious substantial interest (*fictief aanmerkelijk belang*) in the Company within the meaning of chapter 4 of the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*) (“ITA”). Generally, a Shareholder has a substantial interest in the Company if the Shareholder, alone or-in case of an individual-together with a partner for Dutch tax purposes, or any relative by blood or by marriage in the ascending or descending line (including foster children) or either of them, owns or holds, or is deemed to own or hold, certain rights to shares, including rights to directly or indirectly acquire shares, directly or indirectly representing 5% or more of the Company’s issued capital as a whole or of any class of Shares or profit participating certificates (*winstbewijzen*) relating to 5% or more of the Company’s annual profits or 5% or more of the Company’s liquidation proceeds;
- (iii) is an entity that, although it is in principle subject to Dutch corporate income tax under the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*) (“CITA”), is not subject to Dutch corporate income tax or is fully or partly exempt from Dutch corporate income tax (such as a qualifying pension fund as described in Section 5 CITA and a tax exempt investment fund (*vrijgestelde beleggingsinstelling*) as described in Section 6a CITA);

- (iv) is an investment institution (*beleggingsinstelling*) as described in Section 28 CITA, or is an entity that is not tax resident in the Netherlands and that has a function comparable to an investment institution (*beleggingsinstelling*) as described in Section 28 CITA;
- (v) is required to apply the participation exemption (*deelnemingsvrijstelling*) with respect to the Shares (as defined in Section 13 CITA). Generally, a Shareholder is required to apply the participation exemption if it is subject to Dutch corporate income tax and it, or a related entity, holds an interest of 5% or more of the nominal paid-up share capital in the Company; or
- (vi) holds the Shares through an entity which is treated as transparent for Dutch tax purposes, while being treated as a resident under the laws of another state.

### **Withholding Tax**

A Shareholder is generally subject to Dutch dividend withholding tax at a rate of 15% on dividends distributed by the Company. Generally, the Company is responsible for the withholding of such dividend withholding tax at source.

However, a Shareholder will not be subject to Dutch dividend withholding tax on dividends distributed by the Company if, and for as long as, the Company is resident solely in Germany for purposes of the convention between Germany and the Netherlands for the avoidance of double taxation and the prevention of fiscal evasion with respect to taxes on income (the "German Dutch tax treaty"), unless:

- (i) the Shareholder is a Dutch Individual (as defined below) or a Dutch Corporate Entity (as defined below); or
- (ii) the Shareholder is a Non-Dutch Individual (as defined below) or a Non-Dutch Corporate Entity (as defined below) and derives profits from an enterprise, which enterprise is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands, to which the Shares are attributable.

Dividends distributed by the Company include, but are not limited to:

- (i) distributions of profits in cash or in kind, whatever they be named or in whatever form;
- (ii) proceeds from the liquidation of the Company or proceeds from the repurchase of Shares by the Company, other than as a temporary portfolio investment (*tijdelijke belegging*), in excess of the average paid-in capital recognized for Dutch dividend withholding tax purposes;
- (iii) the par value of the Shares issued to a Shareholder or an increase in the par value of the Shares, to the extent that no related contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- (iv) partial repayment of paid-in capital, that is
  - (a) not recognized for Dutch dividend withholding tax purposes, or
  - (b) recognized for Dutch dividend withholding tax purposes, to the extent that the Company has "net profits" (*zuivere winst*), unless
    - the general meeting of shareholders has resolved in advance to make this repayment, and
    - the par value of the Shares concerned has been reduced by an equal amount by way of an amendment to the articles of association of the Company.

The term "net profits" includes anticipated profits that have yet to be realized.

If a Shareholder is an individual that is resident or deemed to be resident in the Netherlands or is an individual that is not resident or deemed to be resident in the Netherlands, but for whom dividends distributed by the Company or income deemed to be derived from the Shares is subject to income tax under the ITA, such Shareholder is generally entitled to a credit for any Dutch dividend withholding tax against his Dutch tax liability and to a refund of any residual Dutch dividend withholding tax. Entities that are resident or deemed to be resident in the Netherlands and entities that are not resident or deemed resident in the Netherlands, but for which dividends distributed by the Company are subject to corporate income tax under the CITA, can only credit Dutch dividend withholding tax up to the total amount of their Dutch corporate income tax liability without taking into account any credit for Dutch dividend withholding tax and gaming tax (*kansspelbelasting*). To the extent the aggregate of the Dutch dividend withholding tax and gaming tax exceeds the aggregate Dutch corporate income tax liability in respect of the relevant year, the excess is not refunded, but carried forward to future years subject to certain restrictions and conditions.

Depending on specific circumstances, a Shareholder resident in a country other than the Netherlands and for whom dividends distributed by the Company or income deemed to be derived from the Shares is not subject to tax under the ITA or the CITA may be entitled to exemptions from, reduction of, or full or partial refund of, Dutch dividend withholding tax under Dutch law, European Union, or the EU, law or treaties for the avoidance of double taxation. According to Dutch domestic anti-dividend stripping rules, no credit against Dutch tax, exemption from, reduction, or refund of Dutch dividend withholding tax will be granted if the recipient of the dividends paid by the Company is not considered to be the beneficial owner (*uiteindelijk gerechtigde*) of those dividends.

The Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting 1965*) ("DWTA"), provides for a non-exhaustive negative description of a beneficial owner. According to the DWTA, a Shareholder will not be considered the beneficial owner of the dividends for this purpose if as a consequence of a combination of transactions:

- (i) a person other than the Shareholder wholly or partly, directly or indirectly, benefits from the dividends;
- (ii) whereby this other person retains or acquires, directly or indirectly, an interest similar to that in the Shares on which the dividends were paid; and
- (iii) that other person is entitled to a credit, reduction or refund of Dutch dividend withholding tax that is less than that of the Shareholder.

Please refer to the paragraph "Risk Factors" for a risk regarding the Company's tax residency and the consequences thereof.

## **Taxes on Income and Capital Gains**

### *Residents of the Netherlands*

The description of certain Dutch tax consequences in this subsection is only intended for the following Shareholders:

- (a) individuals who are resident or deemed to be resident in the Netherlands ("Dutch Individuals"); and
- (b) entities or enterprises that are subject to the CITA and are resident or deemed to be resident in the Netherlands ("Dutch Corporate Entities").

#### *Dutch Individuals engaged or deemed to be engaged in an enterprise or in miscellaneous activities*

Dutch Individuals engaged or deemed to be engaged in an enterprise or in miscellaneous activities (*resultaat uit overige werkzaamheden*) are generally subject to income tax at statutory progressive rates with a maximum of 49.5% (2023) on any benefits derived or deemed to be derived from the Shares, including any capital gains realized on any disposal of the Shares, where those benefits are attributable to:

- (i) an enterprise from which a Dutch Individual derives profits, whether as an entrepreneur (*ondernemer*) or by being co-entitled (*medegerechtigde*) to the net worth of this enterprise other than as an entrepreneur or shareholder; or

- (ii) miscellaneous activities, including activities which are beyond the scope of active portfolio investment activities (*meer dan normaal vermogensbeheer*).

*Dutch Individuals not engaged or deemed to be engaged in an enterprise or in miscellaneous activities*

Generally, the Shares held by a Dutch Individual who is not engaged or deemed to be engaged in an enterprise or in miscellaneous activities, or who is so engaged or deemed to be engaged but the Shares are not attributable to that enterprise or miscellaneous activities and who does not have a substantial or fictitious substantial interest, will be subject to an annual income tax imposed on a fictitious yield on the fair market value of the Shares on 1 January of each calendar year under the regime for savings and investments (*inkomen uit sparen en beleggen*). Irrespective of the actual income or capital gains realized, the annual taxable benefit from a Dutch Individual's assets and liabilities taxed under this regime, including the Shares, is based on fictitious percentages applied to the fair market value of (i) bank savings, (ii) other assets, including the Shares, and (iii) liabilities.

Taxation only occurs if and to the extent the sum of the fair market value of bank savings and other assets minus the fair market value of the liabilities exceeds a certain threshold (*heffingvrij vermogen*). The tax rate under the regime for savings and investments is a flat rate of 32%.

For the calendar year 2023, the fictitious percentages applicable to the first and third categories mentioned above (bank savings and liabilities) have not yet been determined. The fictitious yield percentage applicable to the second category mentioned above (other assets, including the Shares) is 6.17% for the calendar year 2023.

Certain transactions that have the effect of reducing the fictitious yield by shifting net wealth between the aforementioned categories (i) and (ii) or increasing liabilities in any three months period starting before and ending after 1 January of the relevant year will for this purpose be ignored unless the Shareholder can demonstrate that such transactions are implemented for other reasons than tax reasons.

The fictitious percentages referred to above are considered by the Dutch government to be in compliance with a decision of the Dutch Supreme Court of 24 December 2021 (ECLI:NL:HR:2021:1963) regarding the incompatibility of the previous regime for savings and investments with the European Convention on Human Rights. Shareholders are nevertheless advised to consult their tax adviser on whether any tax levied under the current regime for savings and investments, including in respect of the Shares, is in accordance with this convention. *Dutch Corporate Entities*

Dutch Corporate Entities are generally subject to corporate income tax at statutory rates up to 25.8% (2023) on any benefits derived or deemed to be derived from the Shares, including any capital gains realized on their disposal.

***Non-residents of the Netherlands***

The description of certain Dutch tax consequences in this subsection is only intended for the following Shareholders:

- (a) individuals who are not resident and not deemed to be resident in the Netherlands ("Non-Dutch Individuals"); and
- (b) entities that are not resident and not deemed to be resident in the Netherlands ("Non-Dutch Corporate Entities").

*Non-Dutch Individuals*

A Non-Dutch Individual will not be subject to any Dutch taxes on income or capital gains derived from the purchase, ownership and disposal or transfer of the Shares, other than withholding tax as described above, unless:

- (i) the Non-Dutch Individual derives profits from an enterprise, whether as entrepreneur or by being co-entitled to the net worth of this enterprise other than as an entrepreneur or shareholder and this enterprise fully or partly is carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands, to which the Shares are attributable;
- (ii) the Non-Dutch Individual derives benefits from miscellaneous activities carried on in the Netherlands in respect of the Shares, including activities which are beyond the scope of active portfolio investment activities; or
- (iii) the Non-Dutch Individual is entitled to a share—other than by way of securities—in the profits of an enterprise which is effectively managed in the Netherlands and to which enterprise the Shares are attributable.

*Non-Dutch Corporate Entities*

A Non-Dutch Corporate Entity will not be subject to any Dutch taxes on income or capital gains in respect of the purchase, ownership and disposal or transfer of the Shares, other than withholding tax as described above, unless:

- (i) the Non-Dutch Corporate Entity derives profits from an enterprise, which enterprise is, in whole or in part, carried on through a permanent establishment or a permanent representative in the Netherlands, to which the Shares are attributable; or
- (ii) the Non-Dutch Corporate Entity is entitled to a share in the profits of an enterprise or a co-entitlement to the net worth of an enterprise, other than by way of securities, which enterprise is effectively managed in the Netherlands and to which enterprise the Shares are attributable.

Under certain specific circumstances, Dutch taxation rights may be restricted for Non-Dutch Individuals and Non-Dutch Corporate Entities pursuant to treaties for the avoidance of double taxation concluded by the Netherlands.

***Dutch Gift Tax or Inheritance Tax***

No Dutch gift tax or inheritance tax is due in respect of any gift of the Shares by, or inheritance of the Shares on the death of, a Shareholder, unless:

- (i) the Shareholder is resident, or is deemed to be resident, in the Netherlands at the time of the gift or death of the Shareholder;
- (ii) the Shareholder dies within 180 days after the date of the gift of the Shares and was or was deemed to be, resident in the Netherlands at the time of his death but not at the time of the gift; or
- (iii) the gift of the Shares is made under a condition precedent and the Shareholder is resident, or is deemed to be resident, in the Netherlands at the time the condition is fulfilled.

***Other Taxes and Duties***

No other Dutch taxes, including turnover or value added taxes and taxes of a documentary nature, such as capital tax, stamp or registration tax or duty, are payable by, or on behalf of, the Shareholder by reason only of the purchase, ownership and disposal of the Shares.

## **Residency**

A Shareholder will not become a resident or deemed resident of the Netherlands by reason only of holding the Shares.

## **Material U.S. Federal Income Tax Considerations**

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of common shares. It does not describe all tax considerations that may be relevant to a particular person's decision to acquire, own or dispose of the common shares.

This section applies only to a U.S. Holder that holds common shares as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment) for U.S. federal income tax purposes. In addition, it does not set forth all of the U.S. federal income tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or other integrated transaction or persons entering into a constructive sale with respect to the common shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- tax-exempt entities, including an "individual retirement account" or "Roth IRA";
- persons that own or are deemed to own ten percent or more of our shares (by vote or value);
- persons who are subject to Section 451(b) of the Code; or
- persons holding common shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will depend on the status of the partner and the activities of the partner and the partnership. Partnerships holding common shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of the common shares.

This section is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Germany and the United States and the income tax treaty between the Netherlands and the United States (as applicable and as the context requires the "Treaty") all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect. No assurance can be given that the IRS will agree with the views expressed in this discussion, or that a court will not sustain any challenge by the IRS in the event of litigation. We have not obtained, nor do we intend to obtain, a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares, who is eligible for the benefits of the Treaty and who is:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of common shares in their particular circumstances. In particular, because our group includes a U.S. subsidiary, (Affimed Inc., a Delaware corporation) and therefore under current law our non-U.S. subsidiaries (Affimed GmbH and AbCheck s.r.o.) are treated as controlled foreign corporations (regardless of whether we are or are not treated as a controlled foreign corporation), any U.S. Holder that owns or is deemed to own ten percent or more of our shares (by vote or value) is urged to consult its tax advisor regarding the potential application of the "Subpart F income" and "global intangible low-taxed income" rules to an investment in our common shares.

### ***Taxation of Distributions***

We do not currently expect to make distributions on our common shares. In the event that we do make distributions of cash or other property, subject to the passive foreign investment company rules described below, distributions paid on common shares, other than certain pro rata distributions of common shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). If we are not treated as a PFIC with respect to a U.S. Holder and were not treated as a PFIC with respect to the U.S. Holder in the preceding taxable year, for so long as our common shares are listed on Nasdaq or another established securities market in the United States or we are eligible for benefits under the Treaty, dividends paid to such a U.S. Holder that is not a corporation would generally be eligible for taxation as "qualified dividend income" if certain other requirements are met, which is taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holders. The amount of a dividend will include any amounts withheld by us in respect of German or Dutch income taxes. Subject to the passive foreign investment company rules described below, the amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction available to U.S. corporations under the Code. Subject to the passive foreign investment company rules described below, dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.



Subject to applicable limitations and the Final FTC Treasury Regulations (defined below), German or Dutch income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be eligible for credit against the U.S. Holder's U.S. federal income tax liability. German or Dutch taxes withheld in excess of the rate applicable with respect to such U.S. Holder under the Treaty will not be eligible for credit against a U.S. Holder's federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may deduct foreign taxes, including any German or Dutch withholding tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. Finalized Treasury Regulations, which apply to foreign taxes paid or accrued in taxable years beginning on or after December 28, 2021 (the "Final FTC Treasury Regulations"), impose additional requirements for foreign taxes to be eligible for credit and U.S. Holders should consult their tax advisers regarding the availability of foreign tax credits for any amounts withheld with respect to dividends on common shares.

***Sale or Other Disposition of Common Shares***

Subject to the passive foreign investment company rules described below, gain or loss realized on the sale or other disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The Final FTC Treasury Regulations generally preclude U.S. taxpayers from claiming a foreign tax credit with respect to any non-U.S. tax imposed on gains from disposition of common shares, unless the tax is creditable under an applicable income tax treaty. U.S. Holders should consult their tax advisers as to whether the non-U.S. tax on gains may be creditable against the U.S. Holder's U.S. federal income tax on foreign-source income from other sources.

### **Passive Foreign Investment Company Rules**

Under the Code, we may be a PFIC for any taxable year in which, after the application of certain look-through rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of “passive income” or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, “passive income.” Passive income generally includes, among other things, dividends, interest, certain non-active rents and royalties, and capital gains. Although we have not performed a definitive PFIC analysis using U.S. federal income tax principles, based on certain estimates as to composition of our income and assets, including the implied value, based on our market capitalization, of our assets that produce non-passive income, during 2022, including, for this purpose, certain elements of our net working capital, we do not believe that we were a PFIC for our 2022 taxable year. However, there can be no assurance that the IRS will agree with our conclusion. In addition, whether we will be a PFIC in 2023 or any future taxable year is uncertain because, among other things, we currently own a substantial amount of passive assets, including cash, and because the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time and the composition of our assets and income may vary substantially over time. The average quarterly value of our assets for purposes of determining our PFIC status for any taxable year will generally be determined in part by reference to our market capitalization, which has fluctuated and may continue to fluctuate significantly over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year.

The IRS has finalized Treasury Regulations that address various issues related to determining whether a foreign corporation is a PFIC and whether a U.S. shareholder holds PFIC stock and has released proposed Treasury Regulations that address various issues related to determining whether a foreign corporation is a PFIC. These Treasury Regulations and proposed Treasury Regulations (if finalized) may affect whether we are a PFIC in 2022 or in any future year. You should consult your tax adviser regarding the effect, if any, these Treasury Regulations may have, or such proposed Treasury Regulations would have, on the determination of our PFIC status.

In addition, we may, directly or indirectly, hold equity interests in Lower-tier PFICs. Under attribution rules, if we are a PFIC, U.S. Holders will be deemed to own their proportionate shares of Lower-tier PFICs and will be subject to U.S. federal income tax according to the rules described in the following paragraphs on (i) certain distributions by a Lower-tier PFIC and (ii) a disposition of shares of a Lower-tier PFIC, in each case as if the U.S. Holders held such shares directly, even though the U.S. Holders have not received the proceeds of those distributions or dispositions directly.

For so long as we are treated as a PFIC with respect to a U.S. Holder (or were treated as a PFIC with respect to the U.S. Holder in the preceding taxable year), dividends paid to certain non-corporate U.S. Holders will not be eligible for taxation as “qualified dividend income.” In addition, if we were a PFIC for any taxable year during which a U.S. Holder held common shares (assuming such U.S. Holder has not made a timely mark-to-market election, as described below), gain recognized by a U.S. Holder on a sale or other disposition (including certain pledges) of the common shares, or an indirect disposition of shares of a Lower-tier PFIC, would be allocated ratably over the U.S. Holder’s holding period for the common shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the amount allocated to that taxable year. Further, to the extent that any distribution received by a U.S. Holder on its common shares (or a distribution by a Lower-tier PFIC to its shareholder that is deemed to be received by a U.S. Holder) exceeds 125% of the average of the annual distributions on the common shares received during the preceding three years or the U.S. Holder’s holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, described immediately above.

If we are a PFIC for any year during which a U.S. Holder holds common shares, we would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds common shares, even if we ceased to meet the threshold requirements for PFIC status.

A U.S. Holder can avoid certain of the adverse rules described above by making a mark-to-market election with respect to its common shares, provided that the common shares are “marketable.” Common shares will be marketable if they are “regularly traded” on a “qualified exchange” or other market within the meaning of applicable Treasury regulations. Our common shares will be treated as “regularly traded” in any calendar year in which more than a de minimis quantity of the common shares is traded on a qualified exchange on at least 15 days during each calendar quarter. Nasdaq, on which the common shares are currently listed, is a qualified exchange for this purpose. If a U.S. Holder makes the mark-to-market election, it will recognize as ordinary income any excess of the fair market value of the common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder’s tax basis in the common shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of common shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). U.S. Holders should consult their tax advisers regarding the availability and advisability of making a mark-to-market election with respect to their common shares because we may have Lower-tier PFICs for which a mark-to-market election may not be available.

In addition, in order to avoid the application of the foregoing rules, a U.S. Holder can make qualified electing fund elections (any such election, a “QEF Election”) with respect to us and each Lower-tier PFIC in the first taxable year that we and each Lower-tier PFIC are treated as PFICs with respect to the U.S. Holder. A U.S. Holder must make the QEF Election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder’s timely filed U.S. federal income tax return generally for the first taxable year that the entity is treated as a PFIC with respect to the U.S. Holder. A U.S. Holder generally may make a separate election to defer payment of taxes on the undistributed income inclusion under the QEF rules, but if deferred, any such taxes are subject to an interest charge. We currently intend to provide the information necessary for a U.S. investor to make a QEF Election with respect to us and each Lower-tier PFIC that we control for 2022 and for any future years with respect to which we determine that we or any Lower-tier PFIC that we control are or are likely to be a PFIC. If a U.S. Holder makes a QEF Election with respect to us or a Lower-tier PFIC that we control, the U.S. Holder will be currently taxable on its pro rata share of the PFIC’s ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC and will not be required to include such amounts in income when actually distributed by the PFIC. If a U.S. Holder makes a QEF Election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder’s income under the QEF Election will not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its common shares by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed, if any, on the common shares that is not included in its income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of common shares in an amount equal to the difference between the amount realized and its adjusted tax basis in the common shares. U.S. Holders should note that if they make QEF Elections with respect to us and Lower-tier PFICs, if any, they may be required to pay U.S. federal income tax with respect to their common shares for any taxable year significantly in excess of any cash distributions, if any, received on the shares for such taxable year. U.S. Holders should consult their tax advisers regarding making QEF Elections in their particular circumstances.

**In addition, if we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates with respect to dividends paid to certain non-corporate U.S. Holders would not apply. If a U.S. Holder owns common shares during any year in which we are a PFIC, the U.S. Holder must file annual reports containing such information as the U.S. Treasury may require on IRS Form 8621 (or any successor form) with respect to us (regardless of whether a mark-to-market election or QEF Election is made), generally with the U.S. Holder’s federal income tax return for that year, unless otherwise specified in the instructions with respect to such form. U.S. Holders should consult their tax advisers regarding whether we are or were a PFIC and the potential application of the PFIC rules.**

## **Information Reporting with Respect to Foreign Financial Assets**

Certain U.S. Holders who are individuals and certain entities may be required to report information relating to an interest in our common shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisers regarding whether or not they are obligated to report information relating to their ownership and disposition of the common shares.

### ***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

#### **F. Dividends and paying agents**

Not applicable.

#### **G. Statement by experts**

Not applicable.

#### **H. Documents on display**

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including Annual Reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

#### **I. Subsidiary information**

Not applicable.

## **ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT RISK**

See note 25 to the consolidated financial statements as of December 31, 2022 for more information about our exposure to market risks.

## **ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

### **A. Debt securities**

Not applicable.

### **B. Warrants and rights**

Not applicable.

**C. Other securities**

Not applicable.

**D. American Depositary Shares**

Not applicable.

**PART II**

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

**A. Defaults**

No matters to report.

**B. Arrears and delinquencies**

No matters to report.

**ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

**A. Use of Proceeds**

No matters to report.

**ITEM 15. CONTROLS AND PROCEDURES**

**A. Disclosure Controls and Procedures**

As of the end of the period covered by this Annual Report, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) was performed under the supervision and with the participation of our managing board, including our Chief Executive Officer and Chief Financial Officer, our principal executive officer and principal financial officer, respectively. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based on the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, as of the end of the period covered by this Annual Report, in providing a reasonable level of assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods in SEC rules and forms, including providing a reasonable level of assurance that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**B. Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based upon criteria established in *Internal Control – Integrated Framework* (2013) by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

### **C. Attestation Report of the Registered Public Accounting Firm**

KPMG AG Wirtschaftsprüfungsgesellschaft, the independent registered public accounting firm that audited our consolidated financial statements prepared in accordance with International Financial Reporting Standards as issued by the IASB (IFRS) as of and for the year ended December 31, 2022, has also audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2022. Their reports are included in this Annual Report on Form 20-F beginning on page F-2

### **D. Changes in Internal Control over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the financial year ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **ITEM 16. [RESERVED]**

#### **ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our supervisory board has determined that each of Uta Kemmerich-Keil and Harry Welten is an audit committee financial expert, as that term is defined by the SEC, and is independent for the purposes of SEC and Nasdaq rules.

#### **ITEM 16B. CODE OF ETHICS**

##### **Code of Conduct**

We have adopted a Code of Conduct that covers a broad range of matters including the handling of conflicts of interest, compliance issues and other corporate policies such as insider trading and equal opportunity and non-discrimination standards. Our Code of Conduct applies to all of our supervisory directors, managing directors and employees. We have also established a Code of Conduct for business partners. In addition, we have implemented a whistleblowing hotline. We have published our Code of Conduct and Code of Conduct for business partners on our website, [www.affimed.com](http://www.affimed.com).

#### **ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

##### **a) Audit Fees**

Audit fees in 2022 and 2021 amounted to €503,000 and €498,000, respectively, and relate to audit services provided by our principal accountants, KPMG AG Wirtschaftsprüfungsgesellschaft and other KPMG International member firms. The aggregate audit fees include fees and expenses billed or accrued for professional services rendered by the principal accountant for the audit of our annual financial statements, the review of the interim condensed consolidated financial statements, the review of registration statements and comfort letters.

##### **b) Audit-Related Fees**

Audit-Related fees in 2022 and 2021 amounted to €nil and €26,000, respectively, and relate to services provided by our principal accountants, KPMG AG Wirtschaftsprüfungsgesellschaft for the review of Enterprise Resource Planning system migration.

##### **c) Tax Fees**

Tax-Related fees in 2022 and 2021 amounted to €16,330 and €5,000, respectively, and related to consulting services provided in respect of global mobility.

**d) All Other Fees**

None.

**e) Audit Committee's Pre-Approval Policies and Procedures**

The Audit Committee is responsible for the appointment, replacement, compensation, evaluation and oversight of the work of the independent auditors. As part of this responsibility, the Audit Committee pre-approves all audit and non-audit services performed by the independent auditors in order to assure that they do not impair the auditor's independence from the Company.

**f) Audit Work Performed by Other Than Principal Accountant if Greater Than 50%**

Not applicable.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

In 2022, no purchases of our equity securities were made by or on behalf of Affimed or any affiliated purchaser.

**ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

***Summary of Significant Corporate Governance Differences from Nasdaq Listing Standards***

Our common shares are listed on the Nasdaq Global Select Market, or Nasdaq. We are therefore required to comply with certain of the Nasdaq's corporate governance listing standards, or the Nasdaq Standards. As a foreign private issuer, we may follow our home country's corporate governance practices in lieu of certain of the Nasdaq Standards. Our corporate governance practices differ in certain respects from those that U.S. companies must adopt in order to maintain a Nasdaq listing. A brief, general summary of those differences is provided as follows.

*Quorum requirements*

In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders in the United States. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

*Solicitation of proxies*

Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b).



*Compensation Committee*

As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires an issuer to have a compensation committee that, *inter alia*, consists entirely of independent directors.

*Nominating and Corporate Governance Committee*

As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(e), which requires an issuer to have independent director oversight of director nominations.

*Director Compensation*

As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5250(b)(3), which requires an issuer to disclose information regarding third party compensation of its directors or director nominees.

*Shareholder approval*

We have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**PART III**

**ITEM 17. Financial statements**

We have responded to Item 18 in lieu of this item.

**ITEM 18. Financial statements**

Financial Statements are filed as part of this Annual Report, see page F-1.

**ITEM 19. Exhibits**

(a) The following documents are filed as part of this registration statement:

<b>Exhibit No.</b>	<b>Exhibit</b>
1.1	<a href="#">Articles of Association of Affimed N.V. (English translation) (incorporated by reference to Exhibit 1.1 of the Affimed N.V. report on Form 20-F filed with the Commission on April 15, 2021).</a>
2*	<a href="#">Description of rights of each applicable class of securities registered under Section 12 of the Securities Exchange Act of 1934.</a>
4.1††	<a href="#">Research Funding Agreement dated August 15, 2013 between Affimed Therapeutics AG and The Leukemia and Lymphoma Society (incorporated by reference to exhibit 10.6 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).</a>
4.2††	<a href="#">Amendment No. 1 to the Research Funding Agreement, dated April 29, 2014 between Affimed Therapeutics AG and The Leukemia and Lymphoma Society (incorporated by reference to exhibit 10.7 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).</a>
4.3	<a href="#">English language summary of Lease Agreement, dated September 19, 2000 and amendments thereto between Affimed Therapeutics AG and Technologiepark Heidelberg II GmbH &amp; Co. KG (incorporated by reference to exhibit 10.8 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).</a>
4.4	<a href="#">Form of Supervisory Director and Managing Director Indemnification Agreement (incorporated by reference to exhibit 10.16 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on August 19, 2014).</a>
4.5††	<a href="#">Research Collaboration and License Agreement, dated as of August 24, 2018 by and between Affimed GmbH and Genentech, Inc. (incorporated by reference to exhibit 10.1 of the Affimed N.V. report on Form 6-K (File no. 001-36619) filed with the Commission on August 27, 2018).</a>
4.6†	<a href="#">Research Collaboration and License Agreement, dated as of November 3, 2020 by and between Affimed GmbH and NewCo (incorporated by reference to Exhibit 10.1 of the Affimed N.V. report on Form 6-K (File No. 001-36619) filed with the Commission on November 9, 2020).</a>
4.7†	<a href="#">Patent and Technology Licensing Agreement, dated as of December 11, 2020, by and between Affimed GmbH and The Board of Regents of The University of Texas System (incorporated by reference to Exhibit 10.1 of the Affimed N.V. report on Form 6-K (File No. 001-36619) filed with the Commission on April 14, 2021).</a>
4.8	<a href="#">Loan Agreement, dated January 8, 2021, between Affimed GmbH, Affimed N.V. and Silicon Valley Bank (incorporated by reference to Exhibit 4.10 of the Affimed N.V. report on Form 20-F filed with the Commission on April 15, 2021).</a>

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4.9*†	<a href="#">Collaboration Agreement, dated November 1, 2022, between Affimed GmbH and Artiva Biotherapeutics, Inc.</a>
8.1	<a href="#">List of subsidiaries (incorporated by reference to Exhibit 8.1 of the Affimed N.V. report on Form 20-F filed with the Commission on April 15, 2021).</a>
12.1*	<a href="#">Certification of Principal Executive Officer pursuant to 17 CFR 240.13a-14(a).</a>
12.2*	<a href="#">Certification of Principal Financial and Accounting Officer pursuant to 17 CFR 240.13a-14(a).</a>
13.1*	<a href="#">Certification of Principal Executive Officer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350.</a>
13.2*	<a href="#">Certification of Principal Financial and Accounting Officer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350.</a>
15.1*	<a href="#">Consent of KPMG AG Wirtschaftsprüfungsgesellschaft</a>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104. Cover*	Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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\* Filed herewith

† Certain confidential portions of this exhibit have been omitted and replaced with "[\*\*\*\*\*]". Such identified information has been excluded from this exhibit because it (i) is not material and (ii) is the type that the registrant treats as private or confidential.

†† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

(b) Financial Statement

Schedules None.

### Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Date: March 23, 2023

#### 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*

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## Report of Independent Registered Public Accounting Firm

To the Shareholders and Supervisory Board of Affimed N.V.:

### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated statements of financial position of Affimed N.V. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of comprehensive loss, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022, in conformity with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 23, 2023 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### *Critical Audit Matter*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Revenue recognition from collaboration agreements*

As discussed in Note 5 to the consolidated financial statements, the Company recognized revenue in 2022 of €41.3 million, of which €41.2 million relate to revenues from research programs performed as part of collaboration agreements with third parties. As discussed in Note 3, such agreements usually include multiple performance obligations that are satisfied over time and recognized according to the stage of completion measured by reference to costs incurred in relation to anticipated total costs of the research programs.

We identified revenue recognition from collaboration agreements as a critical audit matter. We performed a sensitivity analysis to determine the significant assumptions used to measure the progress of identified performance obligations, which required challenging auditor judgment. Specifically, challenging and subjective auditor judgment was required to evaluate the anticipated total costs of research programs.

The primary procedures we performed to address this critical audit matter included the following. We evaluated the design and tested the operating effectiveness of certain internal controls over the Company's revenue process. This included controls related to significant assumptions, including their development and application, and the monitoring of changes to the assumptions. We evaluated the anticipated total costs of research programs by (1) obtaining and inspecting contractual documents and correspondence with customers and comparing them to management's estimated stage of completion, (2) interviewing program personnel to gain an understanding of the status of program activities to challenge management's estimated stage of completion, (3) obtaining and analyzing documentation, such as external meeting minutes and project plans, to evaluate the reasonableness of management's assumptions regarding anticipated total cost of the research program, and (4) performing a retrospective review of the anticipated versus actual costs and changes in the project plans, if any, including the amount and timing of the change based on internal information or contractual changes, to assess the reliability of planning assumptions.

/s/ KPMG AG Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2014.

Mannheim, Germany

March 23, 2023



## Report of Independent Registered Public Accounting Firm

To the Shareholders and Supervisory Board of Affimed N.V.:

### *Opinion on Internal Control Over Financial Reporting*

We have audited Affimed N.V.'s and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2022 and 2021, the related consolidated statements of comprehensive loss, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements), and our report dated March 23, 2023 expressed an unqualified opinion on those consolidated financial statements.

### *Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### *Definition and Limitations of Internal Control Over Financial Reporting*

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG AG Wirtschaftsprüfungsgesellschaft

Mannheim, Germany

March 23, 2023

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

	Note	2022	2021	2020
<b>Revenue</b>	5	<b>41,353</b>	<b>40,366</b>	<b>28,360</b>
Other income - net	6	1,417	1,310	626
Research and development expenses	7	(98,814)	(81,488)	(49,989)
General and administrative expenses	8	(32,075)	(24,218)	(13,715)
<b>Operating loss</b>		<b>(88,119)</b>	<b>(64,030)</b>	<b>(34,718)</b>
<b>Finance income / (costs) - net</b>	10	<b>2,117</b>	<b>6,509</b>	<b>(6,647)</b>
<b>Loss before tax</b>		<b>(86,002)</b>	<b>(57,521)</b>	<b>(41,365)</b>
Income taxes	11	(2)	(2)	(1)
<b>Loss for the period</b>		<b>(86,004)</b>	<b>(57,523)</b>	<b>(41,366)</b>
<b>Other comprehensive 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	14	(6,047)	(7,693)	(242)
<b>Other comprehensive loss</b>		<b>(6,047)</b>	<b>(7,693)</b>	<b>(242)</b>
<b>Total comprehensive loss</b>		<b>(92,051)</b>	<b>(65,216)</b>	<b>(41,608)</b>
<b>Basic and diluted loss per share in € per share (undiluted = diluted)</b>		<b>(0.60)</b>	<b>(0.48)</b>	<b>(0.50)</b>
<b>Weighted number of common shares outstanding</b>		<b>142,362,294</b>	<b>119,502,384</b>	<b>83,471,559</b>

The Notes are an integral part of these consolidated financial statements.

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

	Note	December 31, 2022	December 31, 2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	12	58	1,607
Leasehold improvements and equipment	13	3,823	3,814
Long-term financial assets	14	0	12,348
Right-of-use assets		561	972
		<u>4,442</u>	<u>18,741</u>
<b>Current assets</b>			
Cash and cash equivalents	15	190,286	197,630
Trade and other receivables	16	2,697	4,809
Inventories		628	421
Other assets and prepaid expenses	17	2,459	3,534
		<u>196,070</u>	<u>206,394</u>
<b>TOTAL ASSETS</b>		<b>200,512</b>	<b>225,135</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
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)
<b>Total equity</b>	18	<b>152,915</b>	<b>135,951</b>
<b>Non-current liabilities</b>			
Borrowings	20	11,687	17,060
Contract liabilities	5	1,083	7,209
Lease liabilities	22	176	368
<b>Total non-current liabilities</b>		<b>12,946</b>	<b>24,637</b>
<b>Current liabilities</b>			
Trade and other payables	21	19,077	18,860
Borrowings	20	5,930	580
Lease liabilities	22	396	683
Contract liabilities	5	9,248	44,424
<b>Total current liabilities</b>		<b>34,651</b>	<b>64,547</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>200,512</b>	<b>225,135</b>

The Notes are an integral part of these consolidated financial statements.

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

	Note	2022	2021	2020
<b>Cash flow from operating activities</b>				
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	19,110	11,820	3,381
— Finance income / (costs) - net	10	(2,117)	(6,509)	6,647
		<u>(66,110)</u>	<u>(50,876)</u>	<u>(30,188)</u>
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
		<u>(104,177)</u>	<u>(85,684)</u>	<u>(19,615)</u>
Interest received		564	0	294
Paid interest		(1,277)	(905)	(78)
Paid income tax		(2)	(2)	(1)
<b>Net cash used in operating activities</b>		<b><u>(104,892)</u></b>	<b><u>(86,591)</u></b>	<b><u>(19,400)</u></b>
<b>Cash flow from investing activities</b>				
Purchase of intangible assets		(37)	(1,654)	(9)
Purchase of leasehold improvements and equipment		(659)	(2,196)	(431)
Cash received from the sale of financial assets	14	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
<b>Net cash generated / (used) for investing activities</b>		<b><u>5,605</u></b>	<b><u>(3,850)</u></b>	<b><u>8,006</u></b>
<b>Cash flow from financing activities</b>				
Proceeds from issue of common shares, including exercise of share-based payment awards	18	95,907	124,460	74,195
Transaction costs related to issue of common shares	18	(6,037)	(7,412)	(2,294)
Proceeds from borrowings	20	0	17,500	0
Transaction costs related to borrowings	20	0	(311)	0
Repayment of lease liabilities	22	(733)	(564)	(521)
Repayment of borrowings	20	(580)	(92)	(2,128)
<b>Cash flow from financing activities</b>		<b><u>88,557</u></b>	<b><u>133,581</u></b>	<b><u>69,252</u></b>
<b>Exchange rate related changes of cash and cash equivalents</b>		<b>3,386</b>	<b>7,636</b>	<b>(6,238)</b>
<b>Net changes to cash and cash equivalents</b>		<b><u>(10,730)</u></b>	<b><u>43,140</u></b>	<b><u>57,858</u></b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b><u>197,630</u></b>	<b><u>146,854</u></b>	<b><u>95,234</u></b>
<b>Cash and cash equivalents at the end of the period</b>		<b><u>190,286</u></b>	<b><u>197,630</u></b>	<b><u>146,854</u></b>

The Notes are an integral part of these consolidated financial statements.

**Affirmed N,V,  
Consolidated statements of changes in equity  
(in € thousand)**

	Note	Issued capital	Capital reserves	Fair value reserves	Accumulated deficit	Total equity
<b>Balance as of January 1, 2020</b>		<b>762</b>	<b>270,451</b>	<b>1,962</b>	<b>(234,508)</b>	<b>38,667</b>
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)
<b>Balance as of December 31, 2020</b>		<b>983</b>	<b>345,164</b>	<b>1,720</b>	<b>(275,874)</b>	<b>71,993</b>
<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		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)
<b>Balance as of December 31, 2021</b>		<b>1,234</b>	<b>474,087</b>	<b>(5,973)</b>	<b>(333,397)</b>	<b>135,951</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	18	259	89,545			89,804
Exercise of share-based payment awards	19	0	101			101
Equity-settled share-based payment awards	19		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)
<b>Balance as of December 31, 2022</b>		<b>1,493</b>	<b>582,843</b>	<b>(1,231)</b>	<b>(430,190)</b>	<b>152,915</b>

The Notes are an integral part of these consolidated financial statements.

Affimed N.V.

Notes to the consolidated financial statements

## 1. Reporting entity

Affimed N.V. is a Dutch company with limited liability (*naamloze vennootschap*) and has its corporate seat in Amsterdam, the Netherlands, registered with the trade register of the Chamber of Commerce (*handelsregister van de Kamer van Koophandel*) under number 60673389.

The consolidated financial statements are comprised of Affimed N.V., and its controlled (and wholly owned) subsidiaries Affimed GmbH, Heidelberg, Germany, AbCheck s.r.o., Plzen, Czech Republic and Affimed Inc., Delaware, USA (collectively "Affimed", the "Company" or the "Group").

Affimed is a clinical-stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies. The Group's product candidates are developed in the field of immuno-oncology, which represents an innovative approach to cancer treatment that seeks to harness the body's own immune defenses to fight tumor cells. Affimed has its own research and development programs, strategic collaborations and service contracts, where the Group is performing research services for third parties.

## 2. Basis of preparation — consolidated financial statements

### Statement of compliance

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS).

The consolidated financial statements were authorized for issuance by the Company's Management Board on March 23, 2023.

### Basis of measurement

The consolidated financial statements have been prepared on the historical cost basis except for financial instruments measured at fair value (see note 14) and monetary assets and liabilities denominated in foreign currencies which are remeasured at period-end exchange rates. The Group did not opt for a valuation of liabilities at fair value through profit or loss.

All amounts included in the consolidated financial statements are reported in thousands of euros (€ thousand) except where otherwise stated.

### Consolidation

The Group controls an entity when it has power over the investee, is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. A subsidiary is consolidated from the date on which control is obtained by the Group. It is de-consolidated from the date control ceases.

Intercompany transactions, balances and unrealized gains/losses on transactions between group companies are eliminated.

### Functional and presentation currency

The consolidated financial statements are presented in euro. The functional currency of the Group's subsidiaries is also the euro. All financial information presented in euro unless otherwise noted has been rounded to the nearest thousand (abbreviated €) or million (abbreviated € million).



Affimed N.V.

Notes to the consolidated financial statements

### **Presentation of consolidated statements of comprehensive loss**

As a clinical-stage biopharmaceutical company with a primary focus on research and development activities, cost of sales and gross profit are not considered meaningful measures for Affimed and therefore are not presented. See note 3 for the Group's accounting policies related to revenue recognition and research and development expenses.

### **Foreign currency transactions**

Transactions denominated in currencies other than the euro are translated at exchange rates at the date of the transaction. Monetary assets and liabilities denominated in currencies other than the euro are translated at the exchange rate at the date of the consolidated statement of financial position.

The foreign currency gain or loss on monetary items is the difference between amortized cost in the functional currency at the beginning of the period, adjusted for effective interest and payments during the period, and the amortized cost in foreign currency translated at the exchange rate at the end of the reporting period.

Foreign currency gains or losses that relate to borrowings, cash and cash equivalents and financial assets, except for financial instruments at fair value through other comprehensive income are presented in the statement of comprehensive loss within 'Finance income / (costs) - net'. All other foreign exchange gains and losses are presented in the statement of comprehensive loss within 'Other income - net'.

### **3. Significant accounting policies**

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements.

#### **Revenue recognition**

The Group generates revenues from the provision of research and development services to third parties based on both Group and third party owned intellectual property. Such services are performed on a "best efforts" basis without a guarantee of technological or commercial success. For some research programs, Affimed entered into collaborations with other companies that provide the Group with funding or other resources such as access to technologies. From time to time, the Group also licenses its intellectual property to third parties who use it to develop product candidates.

Collaboration and license agreements are evaluated to determine whether they involve multiple promises that represent separate performance obligations typically including research programs, platform licenses or intellectual property licenses.

The total consideration is allocated to separate performance obligations based on relative stand-alone selling prices. Usually sales prices for research and development activities and licenses are not directly observable. Therefore, we use estimation techniques, such as an expected cost plus margin approach, to determine stand-alone selling prices for such services and licenses. Margins are estimated based on market trends within the pharmaceutical industry. For licenses of intangible assets where little or no incremental costs are incurred in providing such licenses, a residual approach is used.

Performance obligations from research programs are satisfied over time because the work performed by the Group either enhances a license that the customer already controls or because the work does not result in an asset with an alternative use for the Group due to contractual restrictions.

Therefore, revenue for such performance obligations is recognized according to the stage of completion measured by reference to costs incurred in relation to anticipated total costs of the research program.

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Notes to the consolidated financial statements

Revenue from platform licenses or intellectual property licenses granted are recognized at a point in time if their nature is a right to use the licensed intellectual property as it exists at the point in time at which the license is granted. This is usually the case when there is no significant continuing involvement by the Group. In these cases, revenue is recognized when control of the license is transferred. Control is considered to be transferred when the customer received all necessary documents and information to begin to use and benefit from the license.

Revenue from platform licenses or intellectual property licenses granted are recognized over time if their nature is to access the licensed intellectual property as it exists throughout the license period. This might be the case when there is significant continuing development to address the content of the platform by the Group. In these cases, revenue is recognized on a straight-line basis until the use of the license by the customer ends.

Payments received from customers commonly include non-refundable upfront payments that are initially recognized as a contract liability, and subsequently recognized as revenue as the related performance obligation is fulfilled. The Group concluded that non-refundable upfront payments do not include financing components because the advance payments arise for reasons other than the provision of financing.

In addition, payment terms may also include payments to be received from customers at a later point in time upon the achievement of certain milestones.

Milestone payments are contingent upon the achievement of contractually stipulated targets. The achievement of these targets or milestones depends largely on meeting specific requirements laid out in the respective agreement. Therefore, individual performance obligations are generally determined based on contractually agreed milestones and related payments. Reaching a milestone will result in a cumulative catch up of revenue for the performance to date.

The Group distinguishes between development and registration milestones and sales-based milestones. Whereas development and registration milestone payments are generally recognized when reaching the defined milestones, revenues for sales-based milestones are recognized upon achievement of contractually stipulated underlying revenues.

### **Research and development**

Costs incurred related to research activities are expensed in the period when they are incurred. Costs incurred on development projects are recognized as intangible assets beginning on the date it can be established that it is probable that future economic benefits attributable to the asset will flow to the Group considering its technological and commercial feasibility. Given the current stage of the development of the Group's candidates and technologies, as well as uncertainties regarding successful regulatory approval, no development expenditures have been capitalized in any of the periods presented in these consolidated financial statements. Intellectual property-related costs for patents are part of the expenditure for the research and development projects. Therefore, registration costs for patents are recognized as expensed when incurred as long as the research and development project concerned does not meet the criteria for capitalization.

The Group entered into certain collaborations with shared cost arrangements in respect of specific projects. Costs related to these projects are shared equally between the parties and the recoveries received by the Group are recognized as other income.

### **Employee benefits**

#### **(i) Short-term employee benefits**

Short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided.

Affimed N.V.

Notes to the consolidated financial statements

A liability is recognized for the amount expected to be paid under a short-term cash bonus, if (a) the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee, and (b) the obligation can be estimated reliably.

(ii) Share-based payment transactions

The Group's share-based payment awards outstanding as of December 31, 2022 and 2021, are classified as equity-settled share-based plans. The fair value of share-based equity-settled awards granted to employees is measured at grant date and compensation cost is recognized over the vesting period with a corresponding increase in equity. Share-based payment awards with non-employees are measured and recognized when services are received. Fair value of stock options with service conditions is estimated using the Black-Scholes-Merton formula. The formula determines the value of an option based on input parameters like the value of the underlying instrument, the exercise price, the expected volatility of share price returns, dividends, the risk-free interest rate, the expected forfeiture rate and the time to maturity of the option. The fair value of stock options with market conditions is determined by using a Monte Carlo Simulation incorporating the hurdle (or barrier) that needs to be reached as an additional input parameter. The number of stock options expected to vest is estimated at each measurement date.

(iii) Termination benefits

Termination benefits are expensed when the Group can no longer withdraw the offer of those benefits. If benefits are not expected to be settled wholly within 12 months of the reporting date, then they are discounted.

**Government grants**

The Group receives certain government grants that support its research effort in specific projects. These grants are generally provided in the form of reimbursement of approved costs incurred as defined in the respective grants. Income in respect of grants also includes contributions towards the costs of research and development. Income is recognized when costs under each grant are incurred in accordance with the terms and conditions of the grant and the collectability of the receivable is reasonably assured.

Government grants relating to costs are deferred and recognized in the income statement over the period necessary to match them with the costs they are intended to compensate. When the cash in relation to recognized government grants is not yet received, the amount is included as a receivable on the statement of financial position.

The Group recognizes income from government grants under 'Other income - net' in the consolidated statement of comprehensive loss.

**Leases**

Affimed recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred. Subsequently, the right-of-use asset is depreciated using the straight-line method from the commencement date to the end of the lease term. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain re-measurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, Affimed's incremental borrowing rate. Generally, Affimed uses its incremental borrowing rate as the discount rate.

The Group determines the incremental borrowing rate by obtaining interest rates from various external financing sources and makes certain adjustments to reflect the terms of the lease and the type of the asset leased.

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Notes to the consolidated financial statements

The lease liability is subsequently measured at amortized cost using the effective interest method. It is re-measured when there is a change in future lease payments arising from a change in an index or rate, a change in the estimate of the amount expected to be payable under a residual value guarantee, or as appropriate, changes in the assessment of whether a purchase or extension option is reasonably certain to be exercised or a termination option is reasonably certain not to be exercised.

Affimed has elected not to recognize right-of-use assets and lease liabilities for some short-term leases (leases with less than 12 months of lease term) and right-of-use assets and liabilities for leases of low value assets. Lease payments associated with these leases are recognized as an expense on a straight-line basis over the lease term.

**Finance income and finance costs**

Finance income comprises interest income from interest bearing bank deposits. Interest income is recognized as it accrues using the effective interest method.

Finance costs comprise primarily interest expense on borrowings.

**Financial instruments**

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

(i) Non-derivative financial assets

The Group's non-derivative financial assets include shares, trade and other receivables, other assets and cash and cash equivalents.

Receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Those debt instruments are held to collect solely payments of principal and interest. They are included in current assets and are subsequently carried at amortized cost.

Cash and cash equivalents comprise cash balances and call deposits with original maturities of three months or less.

The Group holds preferred shares in Amphivena Therapeutics Inc. ("Amphivena"), USA, and previously held common shares in Roivant Sciences Ltd ("Roivant"), USA (see note 14). The Group has elected to present changes in fair value of these investments through other comprehensive income.

(ii) Non-derivative financial liabilities

The Group's classes of financial liabilities are borrowings and trade and other payables. The Group initially recognizes non-derivative financial liabilities on the date that they are originated and measures them at amortized cost using the effective interest rate method. The Group derecognizes a financial liability when its contractual obligations are discharged, cancelled or expire.

(iii) Compound financial instruments

The Group entered into a loan agreement pursuant to which it issued warrants to purchase common shares of the Group at the option of the respective holder. The number of shares to be issued does not vary with changes in their fair value.

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Notes to the consolidated financial statements

The liability component of the loan was recognized initially at the fair value of a similar liability without a warrant. The equity component was recognized initially at the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component. Subsequent to initial recognition, the liability component was measured at amortized cost using the effective interest method. The equity component was not re-measured subsequent to initial recognition.

## Impairment

### (i) Trade and other receivables

Trade and other receivables at amortized cost are subject to the expected credit loss model according to IFRS 9. The Group's exposure to credit risk is influenced mainly by the individual characteristics of each customer. However, management also considers the factors that may influence the credit risk of its customer base, including the default risk associated with the industry and country in which customers operate.

Affimed determines the counterparties' lifetime expected credit losses that result from all possible default events over the expected life of a financial instrument based on an estimated rating and corresponding probability of default rates according to the Bloomberg database.

In addition, trade and other receivables are assessed at each reporting date to determine whether there is objective evidence that they are impaired. Trade or other receivables are impaired if objective evidence indicates that a loss event has occurred after the initial recognition of the receivable, and such loss event had a negative effect on the estimated future cash flows of that receivable that can be estimated reliably. Loss events include indications that a debtor is experiencing significant financial difficulty, default or delinquency in interest or principal payments, the probability that they will enter bankruptcy or other financial reorganization.

All receivables are assessed for specific impairment. Losses are recognized in profit or loss and reflected in an allowance account against receivables. When a subsequent event causes the amount of impairment loss to decrease, the decrease in impairment loss is reversed through profit or loss. No impairments or reversals of impairments were recognized in 2022, 2021 or 2020.

### (ii) Intangible assets and leasehold improvements and equipment

Intangible assets that are acquired by the Group and have finite useful lives are measured at cost less accumulated amortization and any accumulated impairment losses. Items of property, plant and equipment are measured at cost, which includes capitalized borrowing costs, less accumulated depreciation and any accumulated impairment losses.

Amortization and depreciation is calculated using the straight-line method over the estimated useful lives, and is recognized in profit or loss. Depreciation and amortization methods and useful lives are reviewed at each reporting date and adjusted if appropriate. The estimated useful lives of property, plant and equipment for current and comparative periods are as follows:

–	Laboratory equipment	5-10 years
–	Office and IT equipment	3-6 years
–	Leasehold improvements	over the term of the lease

Assets that are subject to depreciation or amortization are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount may not be recoverable. An impairment loss is recognized as the amount by which an asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. Non-financial assets that were previously impaired are reviewed for possible reversal of the impairment at each reporting date.

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### **Income taxes**

Income taxes comprise current and deferred tax. Current and deferred taxes are recognized in profit or loss except to the extent that it relates to items recognized directly in equity or in other comprehensive loss.

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the reporting date, and adjustments to taxes payable in respect of previous years.

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for temporary differences associated with assets and liabilities if the transaction which led to their initial recognition is a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss.

Deferred tax is measured at tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date.

Deferred tax assets and liabilities are presented net if there is a legally enforceable right to offset.

A deferred tax asset is recognized for unused tax losses, tax credits and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

### **Fair Value Measurement**

All assets and liabilities for which fair value is recognized in the consolidated financial statements are classified in accordance with the following fair value hierarchy, based on the lowest level input parameter that is significant on the whole for fair value measurement:

- Level 1 — Prices for identical assets or liabilities quoted in active markets (non-adjusted);
- Level 2 — Measurement procedures, in which the lowest level input parameter significant on the whole for fair value measurement is directly or indirectly observable for on the market and which are not included in Level 1; and
- Level 3 — Measurement procedures, in which the lowest level input parameter significant on the whole for fair value measurement is not directly or indirectly observable for on the market.

The carrying amount of all trade and other receivables, other assets and prepaid expenses, cash and cash equivalents, trade and other payables and loans is a reasonable approximation of the fair value and, therefore, information about the fair values of those financial instruments has not been disclosed. The measurement of the fair value of preferred and common shares in other companies held by the group is based on level 1 and level 3 inputs (see note 14). The Group recognises transfers between levels of the fair value hierarchy as at the date at which the change has occurred.

### **Loss per share**

Loss per common share is calculated by dividing the loss for the period by the weighted average number of common shares outstanding during the period.

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As of December 31, 2022, the Group has granted 18,200,984 options and warrants in connection with share-based payment programs (see note 19) and a loan agreement, which could potentially have a dilutive effect but were excluded from the diluted weighted average number of ordinary shares calculation because their effect would have been anti-dilutive due to the net loss generated by the Group.

### **Critical judgments and accounting estimates**

The preparation of the consolidated financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

In preparing these financial statements, the critical judgments made by management in applying the Group's accounting policies resulted in the following accounting estimates:

(i) Share-based payments

The fair value of stock options with service conditions issued by Affimed N.V. is estimated using the Black-Scholes-Merton formula. The formula determines the value of an option based on input parameters like the value of the underlying instrument, the exercise price, the expected volatility of share price returns, dividends, the risk-free interest rate and the time to maturity of the option. The fair value of stock options with market conditions is determined by using a Monte Carlo Simulation incorporating the hurdle (or barrier) that needs to be reached as an additional input parameter. The fair value of share-based equity-settled compensation plans is measured at grant date and compensation cost is recognized over the vesting period with a corresponding increase in equity. The number of stock options expected to vest is estimated at each measurement date.

(ii) Revenue recognition

The Group's contracts with the majority of our customers contain multiple performance obligations. Judgment is required in determining whether a good or service is considered a separate performance obligation. If standalone selling prices are not directly observable, the Group allocates the transaction price to the performance obligations by reference to the expected cost plus a margin. In doing so, observable input data such as internal project plans and margins are used.

The Group has entered into research service agreements, collaboration and license agreements with customers for which non-refundable upfront payments are received for research funding purposes, technology access fees and/or milestone payments. Generally, the Group has continuing performance obligations and therefore upfront payments are initially recognized as a contract liability, and the related revenues are subsequently recognized as the related performance obligation is fulfilled. In this context, the determination of the stage of completion requires judgement, in particular with respect to the anticipated total costs of research programs. Technology access fees are generally initially recognized as a contract liability and subsequently recognized over the expected term of the agreement on a straight-line basis.

The determination of whether a performance obligation is satisfied at a point in time versus over time might also require judgment.



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### New standards and interpretations not yet adopted

The following new standards and amendments to standards are effective for annual periods beginning after December 31, 2022 and have not been applied in preparing these consolidated financial statements.

<u>Standard/interpretation</u>	<u>Effective Date</u> <sup>1</sup>
Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current	January 1, 2024
Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies	January 1, 2023
Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback	January 1, 2024

<sup>1</sup> Shall apply for periods beginning on or after the date shown in the effective date column.

The amended standards are not expected to have a significant effect on the consolidated financial statements of the Group.

#### 4. Segment reporting

##### (i) Information about reportable segment

The Group is active in the discovery, pre-clinical and clinical development of antibodies based on its core technology. The activities are either conducted as own project development or for third party companies. Management of resources and reporting to the chief operating decision maker, being the Management Board, is based on the Group as a whole.

##### (ii) Geographic information

The geographic information below analyses the Group's revenue and non-current assets by country. In presenting the following information, segment revenue has been based on the geographic location of the customers and segment assets were based on the geographic location of the assets.

Discovery activities and research services are conducted in both the Heidelberg and Plzen premises. Pre-clinical and clinical activities are conducted and coordinated from Heidelberg.

<b>Revenue:</b>	<u>2022</u>	<u>2021</u>	<u>2020</u>
Germany	152	742	194
Europe	0	0	2
USA	41,201	39,624	28,164
	<b>41,353</b>	<b>40,366</b>	<b>28,360</b>
<b>Non-current assets as of December 31:</b>	<u>2022</u>	<u>2021</u>	<u>2020</u>
Germany	3,435	4,896	3,796
Czech Republic	1,007	1,306	914
USA	0	12,539	20,216
	<b>4,442</b>	<b>18,741</b>	<b>24,926</b>

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(iii) Major Customers

In 2022 and 2021, revenue with Genentech and Roivant each exceeded 10% of total revenue. In 2020, the Group's revenue with Genentech exceeded 10% of total revenues.

## 5. Revenue

### Collaboration with Genentech

In August 2018, Affimed entered into a strategic collaboration agreement with Genentech Inc. (Genentech), headquartered in San Francisco, USA. Under the terms of the agreement Affimed is providing services related to the development of novel NK cell engager-based immunotherapeutics to treat multiple cancers. The Genentech agreement became effective at the beginning of October 2018. Under the terms of the agreement, Affimed received \$96.0 million (€83.2 million) in an initial upfront payment and committed funding on October 31, 2018.

The Group recognized €18.5 million as revenue in 2022 (2021: €21.6 million, 2020: €26.2 million). As at December 31, 2022, the Group held contract liabilities of €1.7 million (December 31, 2021: €20.2 million, December 31, 2020: €41.9 million), which will be recognized as revenue in subsequent periods.

Under the terms of the agreement, Affimed is eligible to receive up to an additional \$5.0 billion over time, including payments upon achievement of specified development, regulatory and commercial milestones. Affimed is also eligible to receive royalties on any potential sales.

### Collaboration with Roivant

On November 9, 2020 Affimed and Affivant Sciences GmbH (formerly Pharmavant 6 GmbH), a subsidiary of Roivant Sciences Ltd. (Roivant), announced a strategic collaboration agreement which grants Roivant a license to the preclinical molecule AFM32. Under the terms of the agreement, Affimed received \$60 million in upfront consideration, comprised of \$40 million in cash and pre-funded research and development funding, and \$20 million of common shares in Roivant. Affimed is eligible to receive additional proceeds in the form of option fees contingent on the commencement of additional programs contemplated under the agreement. The Group is eligible to receive up to an additional \$2 billion in milestones payments upon achievement of specified development, regulatory and commercial milestones, as well as tiered royalties on net sales.

For the year ended December 31, 2022 the group has recognized €22.7 million (2021: €17.7 million, 2020: €1.4 million) as revenue. As of December 31, 2022, the Group held contract liabilities of €8.6 million (December 31, 2021: €31.3 million, December 31, 2020: €49.0 million), which will be recognized as revenue in subsequent periods as services are provided.

### Research service agreements

The Group has entered into certain research service agreements. These research service agreements provide for non-refundable upfront technology access research funding and milestone payments. The Group recognized revenue of €0.2 million, €1.1 million and €0.6 million during the years ended December 31, 2022, 2021 and 2020 respectively.

### Contract balances

The following table provides information about receivables and contract liabilities from contracts with customers.

	December 31, 2022	December 31, 2021
Receivables	0	150
Contract liabilities	10,331	51,633

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An amount of €41,302 that was recognized in contract liabilities at the beginning of the period was recognized as revenue during the period ended December 31, 2022 (2021: €39,512; 2020: €17,457).

The remaining performance obligations at December 31, 2022 are approximately €10.3 million and are expected to be largely recognized as revenue over the next 12 months (2022: €9.2 million; 2021: €44.4 million), with a smaller portion being realized thereafter (2022: €1.1 million; 2021: €7.2 million).

**Disaggregation of revenue**

	2022	2021	2020
<b>Major service lines:</b>			
Collaboration revenue	41,198	39,301	27,755
Service revenue	155	1,065	605
	<b>41,353</b>	<b>40,366</b>	<b>28,360</b>
<b>Timing on revenue recognition:</b>			
Point in time	0	490	9,180
Over time	41,353	39,876	19,180
	<b>41,353</b>	<b>40,366</b>	<b>28,360</b>

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## 6. Other income and expenses — net

Other income and expenses, net, mainly comprises foreign exchange losses of €99 in 2022 (2021: gains of €125, 2020: gain of €129); income from government grants for research and development projects of €563 in 2022, €344 in 2021, and €348 in 2020 and from research collaborations where costs are shared equally between both parties of €898 (2021: €1,072, 2020: €0).

## 7. Research and development expenses

The following table shows the different types of expenses allocated to research and development costs for the years ended December 31:

	2022	2021	2020
Third-party services	61,943	54,810	29,324
Personnel expenses	29,023	20,532	13,638
Legal, consulting and patent expenses	1,177	1,301	2,380
Cost of materials	2,138	2,152	1,730
Amortization and depreciation	2,639	1,057	834
Other expenses	1,894	1,636	2,083
	<b>98,814</b>	<b>81,488</b>	<b>49,989</b>

Amortization and depreciation includes an impairment of €1.5 million in respect of a technology licence (see note 12).

## 8. General and administrative expenses

The following table shows the different types of expenses allocated to general and administrative costs for the years ended December 31:

	2022	2021	2020
Personnel expenses	15,249	10,713	6,319
Legal, consulting and audit expenses	8,299	8,134	5,601
Insurance expenses	3,493	2,613	904
Other expenses	5,034	2,758	891
	<b>32,075</b>	<b>24,218</b>	<b>13,715</b>

## 9. Employee benefits

The following table shows the items of employee benefits for the years ended December 31:

	2022	2021	2020
Wages and salaries	23,370	17,882	15,081
Social security costs	3,098	2,332	1,847
	<b>26,468</b>	<b>20,214</b>	<b>16,928</b>

The employer's contributions to pension insurance plans of €1,322 (2021: €1,030, 2020: €795) are classified as payments under a defined contribution plan and are recognized as an expense.

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**10. Finance income and finance costs**

The following table shows the items of finance income and costs for the years ended December 31:

	2022	2021	2020
Interest SVB Loan Agreement (see note 20)	(1,630)	(712)	(95)
Foreign exchange differences	3,386	7,636	(6,693)
Interest on certificates of deposit with maturities of more than three months	0	0	186
Other finance income/finance costs - net	361	(415)	(45)
	<b>2,117</b>	<b>6,509</b>	<b>(6,647)</b>

**11. Income taxes**

The Group did not incur any material income tax in the periods presented. As of December 31, 2022, deferred tax assets from differences resulting from intangible assets (€238; 2021: €207), trade and other receivables (€102; 2021: €1,194), borrowings (€26; 2021: €44), lease liabilities (€150; 2021: €206), trade and other payables (€31; 2021: €31), long-term financial assets (€0; 2021: €1,149) and contract liabilities (€0; 2021: €47) have not been recognized as deferred tax assets as no sufficient future taxable profits or offsetting deferred tax liabilities are available. As of December 31, 2022 deferred tax liabilities from temporary differences result mainly from leasehold improvements and equipment and right-of-use assets (€204; 2021: €276), other assets (€0; 2021: €1,054), long-term financial assets (€266; 2021: €0), contract liabilities (€291; 2021: €0) and borrowings (€86; 2021: €93). Deferred tax liabilities are not recognized as there is an excess of deferred tax assets over deferred tax liabilities.

A reconciliation between actual income taxes and the expected tax benefit from the loss before tax multiplied by the Group's applicable tax rate is presented below for the years ended December 31:

	2022	2021	2020
Loss before tax	(86,002)	(57,521)	(41,365)
Income tax benefit at tax rate of 29.825 %	25,650	17,156	12,337
Adjustments of deferred tax assets	(25,022)	(15,850)	(11,196)
Adjustments for local tax rates	23	(62)	(41)
Non-deductible expenses	(755)	(1,434)	(803)
Other	102	188	(298)
<b>Income taxes</b>	<b>(2)</b>	<b>(2)</b>	<b>(1)</b>

In Germany, Affimed has tax losses carried forward of €372.0 million (2021: €288.6 million) for corporate income tax purposes and of €371.0 million (2021: €287.7 million) for trade tax purposes that are available indefinitely for offsetting against future taxable profits of that entity. Restrictions on the utilization of tax losses in case of a change of control of ownership in Affimed were mitigated by the enactment of the Economic Growth Acceleration Act (*Wachstumsbeschleunigungsgesetz 2009*). According to the provisions of this act unused tax losses of a corporation as of the date of a qualified change in ownership are preserved to the extent they are compensated by an excess of the fair value of equity for tax purposes above its carrying amount of the Group. The maximum amount of tax losses at risk of being lost due to ownership changes is approximately €59 million. Deferred tax assets have not been recognized in respect of any losses carried forward as no sufficient taxable profits of Affimed are expected.

Tax losses carried forward of Abcheck s.r.o. amount to €20 as of December 31, 2022 (2021: €20).

**12. Intangible assets**

	Licences	Software	Total
Cost as of January 1, 2022	2,034	293	2,327
Additions	0	37	37
Cost as of December 31, 2022	2,034	330	2,364
Accumulated amortisation/impairment as of January 1, 2022	470	250	720
Amortisation charge for the year	87	23	110
Impairment incurred during the year	1,476	0	1,476
Accumulated amortisation/impairment as of December 31, 2022	2,033	273	2,306
<b>Carrying value as of December 31, 2022</b>	<b>1</b>	<b>57</b>	<b>58</b>

	Licences	Software	Total
Cost as of January 1, 2021	2,032	290	2,322
Additions	2	3	5
Cost as of December 31, 2021	2,034	293	2,327
Accumulated amortisation as of January 1, 2021	382	222	604
Amortisation charge for the year	88	28	116
Accumulated amortisation as of December 31, 2021	470	250	720
<b>Carrying value as of December 31, 2021</b>	<b>1,564</b>	<b>43</b>	<b>1,607</b>

In December 2020, Affimed entered into a patent and technology license agreement (the “MD Anderson License”) providing the Group with an exclusive development and commercialization license. The Group recognized the non-refundable license fee of \$2 million (€1.6 million) as an intangible asset and was amortising the acquisition cost, on a straight line basis, over an estimated useful life of 19 years. In 2022, however, Affimed decided that further development of its ICE® molecules would utilize alternative technologies that would not require the MD Anderson License, as evidenced by Affimed’s agreement with Artiva to develop AFM13 in combination with AB-101. Accordingly, Affimed determined that it was unlikely that the MD Anderson License would be used going forward, and therefore an impairment indicator was identified by management resulting in impairment of the remaining net book value of the license (€1.5 million) to nil.

**13. Leasehold improvement and equipment**

	Leasehold improvements	Laboratory and office equipment	Total
Cost as of January 1, 2022	74	7,321	7,395
Additions	0	658	658
Cost as of December 31, 2022	74	7,979	8,053
Accumulated depreciation as of January 1, 2022	54	3,527	3,581
Depreciation charge for the year	2	647	649
Accumulated depreciation as of December 31, 2022	56	4,174	4,230
<b>Carrying value as of December 31, 2022</b>	<b>18</b>	<b>3,805</b>	<b>3,823</b>

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	Leasehold improvements	Laboratory and office equipment	Total
Cost as of January 1, 2021	74	5,125	5,199
Additions	—	2,196	2,196
Cost as of December 31, 2021	74	7,321	7,395
Accumulated depreciation as of January 1, 2021	47	2,926	2,973
Depreciation charge for the year	7	601	608
Accumulated depreciation as of December 31, 2021	54	3,527	3,581
<b>Carrying value as of December 31, 2021</b>	<b>20</b>	<b>3,794</b>	<b>3,814</b>

**14. Long-term financial assets**

The Group holds preferred shares in Amphivena, which are currently recognized at their fair value of nil. The impairment of the asset was recognized in 2021 based on the decision made by the board of Amphivena to wind down the company. Based on current information, we continue to estimate that the fair value remains at nil (December 31, 2021: nil).

As of December 31, 2021, the long-term financial assets included the Group's investment in Roivant at its fair value of €12.3 million. As at December 31, 2021 the fair value of the shares in Roivant was based on its quoted market price.

In June 2022, a strategic decision was taken to dispose of this investment. These shares were sold at a weighted average selling price of €4.54 (\$4.59) resulting in gross proceeds of €6.3 million (\$6.4 million). The cumulated loss on sale of these shares of €10.8 million, original acquisition price of shares having been €17.1 million, was reclassified within equity from the fair value reserve to the accumulated deficit.

**15. Cash and cash equivalents**

	December 31,	
	2022	2021
Bank balances	190,286	129,972
Call deposits	0	67,658
	<b>190,286</b>	<b>197,630</b>

Call deposits all have original maturities of 3 months or less.

**16. Trade and other receivables**

The trade receivables as of December 31, 2022 and 2021, of €0 and €150, respectively, are all due in the short-term, do not bear interest and are not impaired. Other receivables are all due within the short-term and mainly comprise value-added tax receivables of €1,505 (2021: €2,737).

**17. Other assets and prepaid expenses**

Other assets and prepaid expenses as of December 31, 2022 of €2.5 million (2021: €3.5 million) are short-term in nature, do not bear interest and are not impaired. The other assets and prepaid expenses mainly comprise a prepayment of €1.1 million (2021: €2.9 million) for the reservation of manufacturing capacity, €0 (2021: €0.3 million) as prepayment for manufacturing activities and €0.5 million (2021: €0) prepayment for assets secured for the new premises.



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## 18. Equity

As of December 31, 2022, the share capital of €1,493 (2021: €1,234) is composed of 149,339,335 (2021: 123,419,772) common shares with a par value of €0.01.

In November 2021, the Company implemented a new ATM program providing for sales over time of up to \$100 million of its common shares. As of December 31, 2021, the Company had issued approximately 0.2 million common shares from this new ATM program and generated approximately €1.6 million in net proceeds.

On January 15, 2021, the Group issued 19,166,667 common shares at a price of \$6.00 per share in a public offering, resulting in net proceeds of approximately €88.7 million, incurring €6.1 million in underwriting commissions, legal and consulting expenses which were deducted from equity.

In April 2021, Silicon Valley Bank exercised all of its warrants which were issued in the course of a loan agreement entered into 2016 and repaid by the Company in 2020. Accordingly, the Group issued 173,482 common shares in 2021.

On April 18, 2022, the Company closed its public offering of 22,500,000 common shares, at the public offering price of \$4.00 per share. The exercise of the underwriters' option to purchase over-allotment shares brought the total number of common shares sold by Affimed to 25,875,000. The public offering generated net proceeds of €89.8 million (\$97.0 million), after deducting €6.0 million (\$6.5 million) in underwriting commissions and other offering expenses.

In connection with common share issuances in 2022 an amount of €6.0 million of direct and incremental transaction cost was deducted from equity; shown net of proceeds in the statement of changes in equity.

As of December 31, 2022, authorized share capital of the company amounts to €3,120 (2020: €3,120) and 311,950,000 (2021: 311,950,000) common shares, each with a nominal value of €0.01 per share.

## 19. Share-based payments

In 2014, an equity-settled share-based payment program was established by Affimed N.V. (ESOP 2014). Under this program, the Company granted awards to certain members of the Management Board, certain members of the Company's Supervisory Board, non-employee consultants and employees.

### Share-based payments with service conditions

The majority of the awards vest in installments over three years and can be exercised up to 10 years after the grant date. In 2022 and 2021, the Group granted 4,915,600 and 4,131,076 awards, respectively, to employees, members of the Management Board and members of the Supervisory Board. Fair value of the awards at grant date in 2022 amounts to €14.1 million (\$15.7 million).

During 2022, 277,427 ESOP 2014 awards were cancelled or forfeited due to termination of employment or termination of consulting agreements with non-employees (2021: 385,355), and 43,440 options were exercised at a weighted average exercise price of \$2.52 (2021: 1,114,061 options were exercised at a weighted average exercise price of \$2.19).

As of December 31, 2022, 15,269,734 ESOP 2014 awards were outstanding (December 31, 2021: 10,675,001), 8,510,863 awards (December 31, 2021: 5,422,591) were vested. The options outstanding at December 31, 2022 had an exercise price in the range of \$1.30 to \$13.47 (2021: \$1.30 to \$13.47), a weighted average remaining contractual life of 7.4 years (2021: 7.7 years) and a weighted average exercise price of \$4.91 (2021: \$5.21). In 2022 and 2021, the Group estimated an annual forfeiture rate of 4.0% for unvested options.

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**Share-based payments with market condition**

During 2022, the Company issued 2,825,000 options with market-based performance conditions to members of the Management Board and employees. Each grant consists of three tranches, whereby one-third of the total grant will vest when the volume-weighted average share price over the preceding thirty trading days reaches \$12.00, \$15.00, and \$18.00, respectively. Except with respect to a change of control, these options shall not vest before the first anniversary of the grant date. Fair value of the awards at grant date as of December 31, 2022 amounts to €2.9 million (\$3.2 million) and the contractual lifetime of the options is two years. Any unvested awards on the date that is two years following the grant date will lapse.

**Share-based payment expense**

In 2022, an expense of €19,110 was recognized affecting research and development expenses (€10,351) and general and administrative expenses (€8,759). In 2021, an expense of €11,820 was recognized affecting research and development expenses (€5,892) and general and administrative expenses (€5,928). In 2020, an expense of €3,381 was recognized affecting research and development expenses (€1,524) and general and administrative expenses (€1,857).

**Fair value measurement**

The fair value of options was determined using the Black-Scholes-Merton valuation model. The significant inputs into the valuation model of share based payment grants with service conditions are as follows (weighted average):

	2022	2021
Fair value at grant date	\$ 3.19	\$ 6.18
Share price at grant date	\$ 4.29	\$ 8.18
Exercise price	\$ 4.29	\$ 8.18
Expected volatility	90 %	95 %
Expected life	5.9	5.9
Expected dividends	0.0	0.0
Risk-free interest rate	2.32 %	1.14 %

The fair value of options with market conditions was determined using a Monte Carlo simulation. The significant inputs into the valuation model are as follows (weighted average):

	2022
Fair value at grant date	\$ 1.13
Share price at grant date	\$ 4.58
Exercise price	\$ 4.58
Expected volatility	70 %
Expected life	2.00
Expected dividends	0.00
Risk-free interest rate	2.41 %

Expected volatility is estimated based on the observed daily share price returns of Affimed measured over a historic period equal to the expected life of the awards.

The risk-free interest rates are based on the yield to maturity of U.S. Treasury strips (as best available indication for risk-free rates), for a term equal to the expected life, as measured as of the grant date.

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## 20. Borrowings

### Silicon Valley Bank

In January 2021, the Group entered into a new loan agreement with Silicon Valley Bank German Branch (SVB) which provides Affimed with up to €25 million in term loans in three tranches: €10 million available at closing, an additional €7.5 million upon the achievement of certain conditions, including milestones related to Affimed's pipeline and market capitalization, and a third tranche of €7.5 million upon the achievement of certain additional conditions related to Affimed's pipeline and liquidity. The first tranche of €10 million was drawn in February 2021 and the second tranche of €7.5 million in December 2021. Pursuant to the terms of the agreement, the loan bears interest at the greater of the European Central Bank Base Rate and 0%, plus 5.5%. Affimed is entitled to make interest only payments through December 1, 2022. The loan will mature at the end of November 2025. As of December 31, 2022, the fair value of the liability did not differ significantly from its carrying amount (€17.5 million).

The loan is secured by a pledge of 100% of the Group's ownership interest in Affimed GmbH, all intercompany claims owed to Affimed N.V. by its subsidiaries, and collateral agreements for all bank accounts, inventory, trade receivables and other receivables of Affimed N.V. and Affimed GmbH recognized in the consolidated financial statements with the following book values:

	Book value as of December 31, 2022	
	Consolidated financial statements	thereof assets pledged
Intangible assets*	58	58
Leasehold improvements and equipment	3,823	3,002
Inventories	628	556
Trade and other receivables	2,697	2,090
Cash and cash equivalents	190,286	188,465
<b>Total</b>	<b>197,492</b>	<b>194,171</b>

\* Assignment is subject to the occurrence of a defined trigger event.

### UniCredit Leasing CZ

In April 2019, the Group entered into a loan agreement with UniCredit Leasing CZ for €562. After an initial instalment of €127 in the second quarter of 2019, repayment is effected in monthly instalments of €8. In May 2020, an interest-only-period for 6 months was agreed, extending repayment for 6 months until May 2024. As of December 31, 2022, an amount of €136 (December 31, 2021: €231) was outstanding, of which €96 (December 31, 2021: €94) was classified as current liabilities. As of December 31, 2022 and 2021, the fair value of the liability did not differ significantly from its carrying amount.

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## Reconciliation to cash flows from financing

Movements of liabilities reconcile to cash flows arising from financing activities as follows:

	2022	2021
Balance as of January 1	17,640	323
<b>Changes from financing cash flows</b>		
Proceeds from borrowings	0	17,500
Repayment of borrowings	(580)	(92)
	<b>17,060</b>	<b>17,408</b>
<b>Other Changes</b>		
Changes in capitalized borrowing costs, net	557	(91)
<b>Balance as of December 31</b>	<b>17,617</b>	<b>17,640</b>

### 21. Trade and other payables

Trade and other payables comprise trade payables of €16,731 (2021: €17,085). Other payables mainly comprise payroll and employee related liabilities for withholding taxes and social security contributions of €2,203 (2021: €1,294) and payables due to employees for unused holidays and other accruals. Other payables are normally settled within 30 days.

### 22. Leases

Affimed presents right-of-use assets for offices, laboratories and vehicles leased in a separate line item from the line item "Leasehold improvements and equipment" that presents other assets of the same nature that Affimed owns. The agreements for the existing premises have an average non-cancellable term of between one and four years with renewal options included in some contracts. For equipment leased with contract terms that are short term and/or leases of low-value items the Group has elected not to recognize right-of-use assets and lease liabilities for these leases.

The carrying amounts of right-of-use assets reconcile as follows:

	Carrying amount			Total
	Buildings	Cars	Office equipment	
Balance as of January 1, 2022	942	21	9	972
Depreciation charge for the year	(650)	(9)	(6)	(665)
Additions to right-of-use assets	254	0	0	254
<b>Balance as of December 31, 2022</b>	<b>546</b>	<b>12</b>	<b>3</b>	<b>561</b>

	Carrying amount			Total
	Buildings	Cars	Office equipment	
Balance as of January 1, 2021	923	2	15	940
Depreciation charge for the year	(595)	(8)	(6)	(609)
Additions to right-of-use assets	614	27	0	641
<b>Balance as of December 31, 2021</b>	<b>942</b>	<b>21</b>	<b>9</b>	<b>972</b>

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Cash outflow related to leases are as follows:

	2022	2021
Repayment of lease liabilities	733	564
Interest on lease liabilities	31	46
Short-term lease payments	23	23
<b>Cash outflow from leasing</b>	<b>787</b>	<b>633</b>

Future contractually agreed undiscounted lease payments are as follows:

	2022	2021
Payments within one year	631	708
Payments between one and five years	180	379
	<b>811</b>	<b>1,087</b>

Movements of lease liabilities reconcile to cash flows arising from financing activities as follows:

	2022	2021
Balance as of January 1	1,051	974
<b>Changes from financing cash flows</b>		
Repayment of lease liabilities	(733)	(564)
	<b>(733)</b>	<b>(564)</b>
<b>Other Changes</b>		
New lease contracts	254	641
	<b>254</b>	<b>641</b>
<b>Balance as of December 31</b>	<b>572</b>	<b>1,051</b>

### 23. Other commitments and contingencies

Commitments

The Group plans to move to new facilities in 2023 and has entered into a lease contract for offices and laboratories with handover taking place approximately mid-2023. Expected payments include monthly rent of €141, an anticipated one-time payment of €1,170 for laboratory construction and a security deposit of €503. The contractual lease term is ten years including a cancellation option after 5 years with an expected start mid-2023. The terms provide for renewal options.

Contingencies

Affimed has entered into various license agreements that contingently trigger payments upon achievement of certain milestones and royalty payments upon commercialization of a product in the future.

### 24. Related parties

Transactions with key management personnel

The compensation of managing directors comprised of the following:

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	2022	2021	2020
Short-term employee benefits	3,662	3,633	2,936
Share-based payments	6,732	5,235	1,848
	<b>10,394</b>	<b>8,868</b>	<b>4,784</b>

Remuneration of Affimed's managing directors comprises fixed and variable components and share-based payment awards. In addition, the managing directors receive supplementary benefits such as fringe benefits and allowances. In the case of an early termination, the managing directors receive a severance.

The supervisory board directors of Affimed N.V. received compensation for their services on the supervisory board of €431 (2021: €392; 2020: €364). In 2022, the Group recognized expenses for share-based payments for supervisory board members of €1,370 (2021: €847, 2020: €293).

The following table provides the total amounts of outstanding balances for supervisory board compensation and expense reimbursement related to managing directors:

	Outstanding balances	
	December 31, 2022	December 31, 2021
Adi Hoess	1	5
Wolfgang Fischer	2	—
Arndt Schottelius	3	—
Thomas Hecht	21	19
Mathieu Simon	10	8
Ferdinand Verdonck <sup>1</sup>	—	(1)
Ulrich Grau	26	16
Bernhard Ehmer	17	20
Harry Welten	8	10
Annalisa Jenkins	11	9
Uta Kemmerich-Keil	18	19

<sup>1</sup> left the Supervisory Board in June 2021.

## 25. Financial risk management

### (i) Financial risk management objectives and policies

The Group's principal financial instruments comprise cash and cash equivalents, certificates of deposit at commercial banks and investor loans presented in borrowings. The main purpose of these financial instruments is to raise funds for the Group's operations. The Group has various other financial assets and liabilities such as trade and other receivables and trade and other payables, which arise directly from its operations.

The Group holds investments in financial fixed assets which were obtained through collaboration agreements with external parties and do not relate to investing activities in order to generate financial income.

The main risks arising from the Group's financial instruments are credit risk, interest rate risk, liquidity risk and foreign currency risk. The measures taken by management to manage each of these risks are summarized below.

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### (ii) Credit risk

The Group's financial assets comprise to a large extent cash and cash equivalents. In addition, financial assets include shares and trade and other receivables. The total carrying amount of shares (€ nil, 2021: €12.3 million), cash and cash equivalents (€190.3 million, 2021: € 197.6 million) and trade and other receivables (€2.7 million, 2021: €4.8 million) represents the maximum credit exposure of €193.0 million (2021: €214.7 million).

The cash and cash equivalents are held with banks, which are rated AA3 to AA2 based on Standard & Poor's and Moody's.

### (iii) Interest rate risk

The Group's interest rate risk arises from cash accounts.

Market interest rates on cash and cash equivalents as well as on term deposits were low, and in some cases negative, resulting in net interest income of €401 (2021: interest expense of €358). A shift in interest rates (increase or decrease) could potentially have a material impact on the loss of the Group.

### (iv) Other price risks

The fair value of the shares in Amphivena depends on the estimated share price, however as the shares are currently reflected at nil, no material exposure exists.

### (v) Foreign currency risk

Foreign exchange risk arises when future commercial transactions or recognized assets or liabilities are denominated in a currency that is not the entity's functional currency.

The Group's entities are mainly exposed to Czech Koruna (CZK), US Dollars (USD) and British Pound (GBP). The net exposure as of December 31, 2022 was €28,694 (2021: €53,487) and mainly relates to US Dollars.

In 2022, if the Euro had weakened/strengthened by 10% against the US dollar with all other variables held constant, the loss would have been €3,270 (2021: €5,482) higher/lower, mainly as a result of foreign exchange gains/losses on remeasurement of US dollar-denominated financial assets. The Group considers a shift in the exchange rates of 10% as a realistic scenario.

Loss is more sensitive to movement in exchange rates shifts in 2022 than in 2021 because of the increased volume of US dollar-denominated transactions.

The following significant exchange rates have been applied during the year:

	2022	2021	2020
	CZK or USD or GBP/EUR	CZK or USD or GBP/EUR	CZK or USD or GBP/EUR
CZK - Average Rate	0.04071	0.03900	0.03780
CZK - Spot rate	0.04147	0.04023	0.03811
USD - Average Rate	0.94967	0.84552	0.87550
USD - Spot rate	0.93756	0.88292	0.81493
GBP - Average Rate	1.17266	1.16333	1.12397
GBP - Spot rate	1.12748	1.19008	1.11231



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(vi) Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulties in meeting the obligations associated with its financial liabilities which are normally settled by delivering cash. The Group's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due.

The Group continually monitors its risk of a shortage of funds using short and mid-term liquidity planning. This takes account of the expected cash flows from all activities. The supervisory board undertakes regular reviews of the budget.

In 2022, 2021 and 2020, Affimed raised significant funding that it estimates will enable the Group to fund operating expenses and capital expenditure requirements into 2025.

In May 2020, the Company implemented an at-the-market ("ATM") program providing for the sales over time of up to \$50,000,000 of its common shares. The Company issued approximately 12.5 million common shares under this ATM program, generating net proceeds of approximately €34.5 million.

In November 2020, the Company implemented a new ATM program providing for additional sales over time of up to \$75,000,000 of common shares. As of December 31, 2021, the Company had issued approximately 4.4 million (2020: 7.9 million) shares, generating approximately €24.4 million (2020: €34.5 million) in net proceeds.

On January 15, 2021 the Company issued 19,166,667 common shares at a price of \$6.00 per share in a public offering resulting in gross proceeds before deducting underwriting discounts and commissions and estimated expenses of the offering of \$115 million.

In January 2021, the Group entered into a loan agreement with Silicon Valley Bank for up to €25 million, of which the Group has drawn €17.5 million in 2021.

In November 2021, Affimed filed a "shelf registration statement" with the SEC in order to offer and sell securities to the public in multiple, future offerings with indeterminate amount.

In November 2021, the Company implemented a new ATM program providing for additional sales over time of up to \$100 million of its common shares. As of December 31, 2021, the Company had issued approximately 0.2 million shares and generated approximately €1.6 million in net proceeds from this new ATM program.

On April 18, 2022, the Company closed its public offering of 22,500,000 common shares, at the public offering price of \$4.00 per share. The exercise of the underwriters' option to purchase over-allotment shares brought the total number of common shares sold by Affimed to 25,875,000. The public offering generated net proceeds of €89.8 million (\$97.0 million), after deducting €6.0 million (\$6.5 million) in underwriting commissions and other offering expenses.

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The Group expects that further funding will be required to complete the development of the existing product candidates. Further, funding will also be required to commercialize the products if regulatory approval is received.

The contractual maturities of Borrowings are as follows:

	<u>2022</u>	<u>2021</u>
Payments within one year	5,930	580
Payments between one and five years	12,752	18,682
	<b>18,682</b>	<b>19,262</b>

(vii) Capital management

The primary objective of the Group's capital management is to ensure that it maintains its liquidity in order to finance its operating activities and meet its liabilities when due.

The Group manages its capital structure primarily through equity.

**26. Subsequent events**

Cash, Cash Equivalents, and Borrowings with Silicon Valley Bank

As at, and subsequent to December 31, 2022, the Company had cash and cash equivalents that were deposited with Silicon Valley Bank Santa Clara, California ("SVB US") and Silicon Valley Bank UK Limited ("SVB UK"). On March 10, 2023, SVB US was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. On March 13, 2023, FDIC transferred all deposits and substantially all assets of SVB US, to a newly created, full-service FDIC-operated 'bridge bank' ("Silicon Valley Bridge Bank") in an action designed to protect all depositors of SVB US. On March 13, 2023, the Bank of England, in consultation with the Prudential Regulation Authority, HM Treasury and the Financial Conduct Authority, has taken the decision to sell SVB UK to HSBC UK Bank Plc. Meanwhile, the Company continues to have full access to the cash and cash equivalents held on deposit at Silicon Valley Bridge Bank and SVB UK. Furthermore, as described in Note 20, the Company has a loan agreement with SVB US Germany Branch. On March 20, 2023, Silicon Valley Bridge Bank was granted permission to conduct the lending business previously operated by SVB US Germany Branch through its German branch, SVB Germany. Overall, the Company expects that the foregoing will not have an impact on the Company's business activities.

**Description of rights of each applicable class of securities  
registered under Section 12 of the Securities Exchange Act of 1934**

As of December 31, 2022, Affimed N.V.'s ("Affimed," "we," "our" or "us") common shares were registered under Section 12 of the Securities Exchange Act of 1934, as amended. Our common shares are listed on The Nasdaq Global Market ("Nasdaq") under the trading symbol "AFMD."

The following summary of the general terms and provisions of our common shares does not purport to be complete and is subject to and qualified in its entirety by reference to our articles of association (the "Articles"), which are incorporated herein by reference to Exhibit 1.1 to our Report on Form 20-F filed with the U.S. Securities and Exchange Commission on April 15, 2021.

**1. *Type and Class of Securities (Item 9.A.5)***

Our common shares are issued in registered form and our Articles do not provide for the issuance of share certificates. As of March 15, 2023, we had 149,339,335 common shares issued and outstanding. All of the issued and outstanding common shares are duly authorized, validly issued and fully paid. Our authorized share capital currently amounts to €3,119,500, divided into 311,950,000 common shares, each with a par value of €0.01. Under Dutch law, our authorized share capital is the maximum capital that we may issue without amending our Articles.

Under our Articles, there are no restrictions on the transferability of our common shares.

Almost all of our common shares are held through the Depository Trust Company ("DTC"). Cede and Company, a specialist United States financial institution that processes transfers of stock certificates on behalf of DTC, is the technical shareholder of record for our issued common shares held by DTC participants. Our shareholders owning common shares through DTC do not themselves hold direct property rights in our common shares, but rather have contractual rights in such shares that are part of a chain of contractual rights involving Cede and Company. Each person owning common shares held through DTC must rely on the procedures of DTC and on institutions that have accounts with DTC to exercise any rights of a holder of the common shares.

**2. *Pre-emptive Rights (Item 9.A.3)***

Under Dutch law, upon the issue of common shares, each holder of common shares shall have a preemptive right to acquire such newly issued shares in proportion to the aggregate amount of such holder's common shares, it being understood that this preemptive right shall not apply to (i) the issuance of shares to employees of the company or employees of a group company; and (ii) the issuance of shares against payment in kind. Under our Articles, if and insofar as the management board is not authorized to limit or exclude preemptive rights, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting of shareholders upon proposal of the management board, which proposal has been approved by the supervisory board. The management board, subject to approval of the supervisory board, may also resolve to restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting of shareholders. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting of shareholders to restrict or exclude the preemptive rights or to designate the management board as the authorized body to do so requires a majority of not less than two-thirds of the votes cast, if less than one-half of our issued share capital is represented at the meeting.

At a general meeting held on June 25, 2019, the general meeting of shareholders authorized our management board, subject to the approval of our supervisory board, for a period of five years from the date of the meeting (up to and including June 25, 2024) to restrict or exclude pre-emptive rights accruing to shareholders in connection with the issue of common shares and/or rights to subscribe for common shares in relation to any issuance or granting of rights to subscribe for common shares in the share capital of Affimed, up to the maximum number of common shares that can be issued under the size of the authorized share capital of Affimed as per the date of adoption of such resolution.

**3. *Limitations or Qualifications (Item 9.A.6)***

Not applicable.

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**4. Other Rights (Item 9.A.7)**

Not applicable.

**5. Rights and Restrictions (Item 10.B.3)**

Dividend Rights and Rights to Share in Profits

Dutch law provides that dividends may be distributed after adoption of the annual accounts by the general meeting of shareholders from which it appears that such dividend distribution is allowed. Moreover, dividends may be distributed only to the extent the shareholders' equity exceeds the amount of the paid-up and called-up part of the issued share capital and the reserves that must be maintained under the law or the articles of association. Interim dividends may be declared as provided in the articles of association and may be distributed to the extent that the shareholders' equity exceeds the amount of the issued and paid-up and called-up part of the issued share capital and the required legal reserves as described above as apparent from our financial statements. Under the Articles, the management board may resolve, subject to the approval of the supervisory board, to reserve the profits or part of the profits. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders. We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The management board may resolve, with the approval of the supervisory board, to make interim distributions to the shareholders if an interim statement of assets and liabilities shows that Affimed's shareholders' equity exceeds the sum of the paid-up and called-up part of the capital and the reserves which must be maintained by Dutch law.

Dividends and other distributions shall be made payable no later than thirty days after the date when they were declared, unless the corporate body authorized to declare the dividend determines a different date. Claims to dividends and other distribution not made within five years from the date that such dividends or distributions became payable, shall be forfeited to us (*verjaring*) and shall be carried to the reserves.

Liquidation

Upon liquidation, the surplus assets of Affimed remaining after satisfaction of all its debts will be divided, in accordance with the provisions of section 2:23b of the Dutch Civil Code (the "DCC") for the benefit of the shareholders in proportion to the nominal value of shares held by each of them.

Voting Rights

In accordance with Dutch law and our Articles, each issued common share confers the right to cast one vote at the general meeting of shareholders. Each holder of shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

In accordance with our Articles, for each general meeting of shareholders, the management board may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting of shareholders. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting.

Redemption Provisions

Under Dutch law, when issuing shares, a public company with limited liability such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company with limited liability may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity less the payment required to make the acquisition does not fall below the sum of paid-up and called-up capital and any reserves required by Dutch law or its articles of association and (ii) the company and its subsidiaries would not thereafter hold shares or hold a pledge over shares with an aggregate par value exceeding 50% of its then current issued share capital. Such company may only acquire

its own shares if its general meeting of shareholders has granted the management board the authority to effect such acquisitions. An acquisition of common shares for a consideration must be authorized by our general meeting of shareholders. Such authorization may be granted for a maximum period of 18 months and must specify the number of common shares that may be acquired, the manner in which common shares may be acquired and the price limits within which common shares may be acquired. Authorization is not required for the acquisition of common shares in order to transfer them to our employees. The actual acquisition may only be effected by a resolution of our management board. At the general meeting held on June 22, 2022, the general meeting of shareholders authorized our management board acting with the approval of our supervisory board, for a period of 18 months (until December 22, 2023) to cause the repurchase of common shares by us of up to 10% of our issued share capital, for a price per share not exceeding 110% of the most recent closing price of a common share on any stock exchange where the common shares are listed.

No authorization of the general meeting of shareholders is required if common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee stock purchase plan.

If we would decide to repurchase any of our shares, no votes could be cast at a general meeting of shareholders on the shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge.

**6. Requirements for Amendments (Item 10.B.4)**

A resolution to amend our Articles may only be adopted by the general meeting at the proposal of the management board with the prior approval of the supervisory board.

**7. Limitations on the Rights to Own Shares (Item 10.B.6)**

Under our Articles, there is no restriction on the ownership of our shares. Most of our common shares are held through DTC and therefore the shareholders owning their shares through DTC do not themselves hold direct property rights in our common shares, but rather have contractual rights in such shares that are part of a chain of contractual rights involving Cede and Company, a specialist United States financial institution that processes transfers of stock certificates on behalf of DTC. Each person owning common shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares.

**8. Provisions Affecting Any Change of Control (Item 10.B.7)**

Various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. We have adopted several provisions that may have the effect of making a takeover of Affimed more difficult or less attractive, including:

- the staggered four-year terms of our supervisory directors, as a result of which only approximately one-fourth of our supervisory directors will be subject to election in any one year;
- a provision that our managing directors and supervisory directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our outstanding share capital if such removal is not proposed by our supervisory board;
- requirements that certain matters, including an amendment of our Articles, may only be brought to our shareholders for a vote upon a proposal by our management board that has been approved by our supervisory board; and

- a statutory response period. Under Dutch law, the management board can invoke a response period by which a shareholder is prevented from convening a general meeting putting new items on the agenda. As per May 1, 2021, a bill took effect extending the statutory response period from 180 to 250 days.

**9. Ownership Threshold (Item 10.B.8)**

Not applicable.

**10. Differences Between the Laws of Different Jurisdictions (Item 10.B.9)**

Set forth below is a summary of certain significant differences between the law applicable to us and the laws applicable to companies incorporated in the United States and their shareholders. Although we believe this summary is materially accurate, the summary is subject to Dutch law, including Book 2 of the DCC and the Dutch Corporate Governance Code (the “DCGC”) and Delaware corporation law, including the Delaware General Corporation Law.

a) Corporate Governance

Duties of Directors

*The Netherlands.* We have a two-tier board structure consisting of our supervisory board (*raad van commissarissen*) and a separate management board (*raad van bestuur*).

Under Dutch law, the management board is collectively responsible for the management and the strategy, policy and operations of the company. The supervisory board is responsible for supervising the conduct of and providing advice to the management board and for supervising the business generally. Furthermore, each member of the management board and the supervisory board has a duty to act in the corporate interest of the company and the business connected with it. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, whereby the circumstances generally dictate how such duty is to be applied.

*Delaware.* The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Director Terms

*The Netherlands.* Managing directors and supervisory directors of a Dutch listed company are generally appointed for an individual term of a maximum of four years. There is no limit to the number of consecutive terms managing directors may serve. Following the DCGC, supervisory directors of a Dutch listed company are appointed for a period of four years and may then be reappointed once for another four-year period. The supervisory board member may then subsequently be reappointed for a period of two years, which appointment may be extended by at most two years.

Our managing directors are appointed by the general meeting of shareholders pursuant to a binding nomination by the supervisory board. The general meeting may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, representing more than one-half of the issued share capital. If the binding nomination is not overruled in accordance with the preceding sentence, the person

proposed for appointment will have been appointed. If the general meeting overrules the binding nomination, the supervisory board shall make a new nomination.

Our supervisory directors are also appointed by the general meeting of shareholders upon a binding nomination by the supervisory board. The general meeting may at all times overrule the binding nomination by a two-thirds majority of the votes cast, representing more than one-half of the issued share capital. If the binding nomination is not overruled in accordance with the preceding sentence, the person proposed for appointment will have been appointed. If the general meeting overrules the binding nomination, the supervisory board shall make a new nomination.

There are no restrictions on the number of reelections of our management directors. Pursuant to the Articles, a supervisory director shall be appointed for a maximum term of four years, and may be reappointed for a term of not more than four years at a time. A supervisory director may be a supervisory director for a period not longer than twelve years, unless the general meeting of shareholders resolves otherwise. Under the DCGC, in the event of a reappointment of a supervisory director after he or she has served as supervisory director for eight years, the supervisory board report should include the reasons for such reappointment. As a result of our supervisory directors' staggered four-year term of appointment, approximately one-fourth of our supervisory directors will be subject to election in any one year.

The general meeting of shareholders shall at all times be entitled to suspend or dismiss a member of the management board or supervisory board. The general meeting of shareholders may only adopt a resolution to suspend or dismiss such a member with a two-thirds majority of the votes cast, if such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board, in which case a simple majority is sufficient. The supervisory board may at all times suspend (but not dismiss) a member of the management board.

*Delaware.* The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

#### Director Vacancies

*The Netherlands.* Under Dutch law, new managing directors and supervisory directors are generally appointed by the general meeting of shareholders.

Under our Articles, in case of a vacancy or vacancies of one or more managing directors, the remaining managing directors shall temporarily be in charge of the management, without prejudice to the right of the supervisory board to replace the managing director with a temporary managing director. In the case of vacancies for all managing directors, the supervisory board shall temporarily be in charge of the management; the supervisory board shall be authorized to designate one or more temporary managing directors. In the case of a vacancy or vacancies of one or more supervisory directors, the remaining supervisory directors shall temporarily be in charge of the supervision, without prejudice to the right of the general meeting to appoint a temporary member of the supervisory board to replace the member of the supervisory board concerned. In the case of vacancies for all supervisory directors, the management board shall as soon as possible take the necessary measures to make arrangements, without prejudice to the right of the general meeting to appoint one or more temporary supervisory directors to replace the supervisory director(s) concerned. The person(s) designated for this purpose shall take the necessary measures to make a definitive arrangement.

*Delaware.* The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.



### Conflict-of-Interest Transactions

*The Netherlands.* Pursuant to Dutch law and our Articles, a managing director or a supervisory director shall not take part in the deliberations and the decision-making process of the management board or the supervisory board, as applicable, if he or she has a direct or indirect personal conflict of interest with the company or the business connected with it. Our Articles provide that if as a result of the conflict of interest of managing directors no resolution of the management board can be adopted, the resolution is adopted by the supervisory board. If as a result of the conflict of interest of supervisory directors no resolution of the supervisory board can be adopted, the resolution can nonetheless be adopted by the supervisory board. In that case, each supervisory board member is entitled to participate in the discussion and decision making process of the supervisory board and to cast a vote.

*Delaware.* The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

### Proxy Voting by Directors

*The Netherlands.* Under our Articles, at a meeting of the management board, a managing director may only be represented by another managing director holding a written proxy. At a meeting of the supervisory board, a supervisory director may only be represented by another supervisory director holding a written proxy.

*Delaware.* A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

#### b) Dutch Corporate Governance Code

The DCGC contains both principles and best practice provisions for management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. As a Dutch company, we are subject to the DCGC and are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the DCGC in our annual report. Our deviations from the DCGC are summarized below.

In December 2022, the Corporate Governance Code Monitoring Committee has published an updated version of the DCGC. The updated DCGC took effect on January 1, 2023 and the Company must start reporting on compliance with the updated DCGC in its annual report covering the financial year 2023. A copy of the DCGC can be found on [www.mccg.nl](http://www.mccg.nl) (which website is not incorporated by reference into this prospectus).

### Remuneration

- We have granted and intend to grant options and restricted stock units in the future to members of our management board. These options provide for vesting conditions which allow exercise of one third of the options after the first anniversary of the grant date, which qualifies as a deviation from best practice provision 3.1.2 of the DCGC. Such vesting conditions are market practice among companies listed on Nasdaq. We are in competition with other companies in this field and intend to maintain an attractive compensation package for its current and any future management board members.
- We have granted and intend to grant options and restricted stock units in the future to members of our supervisory board, which qualifies as a deviation from best practice provision 3.3.2 of the DCGC.

Such remuneration is in accordance with Nasdaq corporate governance requirements and market practice among companies listed on Nasdaq. We are in competition with other companies in this field and intend to maintain an attractive compensation package for our current and any future supervisory board members. The number of option rights granted to each supervisory board member is determined by the general meeting of shareholders.

- The compensation committee of the Supervisory Board has not prepared a remuneration report, which qualifies as a deviation from best practice provision 3.4.1 of the DCGC. Instead, an overview of the implementation and planning of the remuneration of managing and supervisory directors is described in more detail in our Annual Report on Form 20-F filed with the SEC on March 23, 2023 (available on our website at <http://www.affimed.com/sec>) (our website is not incorporated by reference in this prospectus).
- The severance payments for our managing directors may exceed 100% of their annual fixed salary. This is a deviation from best practice provisions 3.2.3 of the DCGC.

#### Board nominations and shareholder voting

- Pursuant to our Articles, the supervisory board will nominate one or more candidates for each vacant seat on the management board or the supervisory board. A resolution of our general meeting of shareholders to appoint a member of the management board or the supervisory board other than pursuant to a nomination by our supervisory board requires at least two-thirds of the votes cast representing more than half of our issued share capital, which qualifies as a deviation from best practice provision 4.3.3 of the DCGC. Although a deviation from the provision 4.3.3 of the DCGC, the supervisory board and the management board hold the view that these provisions will enhance the continuity of our management and policies.

#### Chairman of the compensation committee

- Until June 2020, Thomas Hecht, chairman of our supervisory board, chaired the compensation committee, which qualified as a deviation from best practice provision 2.3.4 of the DCGC. We have opted out of the director independence requirements under applicable Nasdaq rules.

#### c) Shareholder Rights

#### Voting Rights

*The Netherlands.* In accordance with Dutch law and our Articles, each issued common share confers the right to cast one vote at the general meeting of shareholders. Each holder of shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

In accordance with our Articles, for each general meeting of shareholders, the management board may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting of shareholders. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting.

*Delaware.* Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is

given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

#### Shareholder Proposals

*The Netherlands.* Pursuant to our Articles and in accordance with Dutch law, general meetings of shareholders will be held whenever our supervisory board or management board deems such to be necessary. Pursuant to Dutch law, one or more shareholders representing at least ten percent of the issued capital may, on their application, be authorized by a Dutch district court to convene a general meeting of shareholders. The district court shall disallow the application if it does not appear that the applicants have previously requested the management board and the supervisory board to convene a general meeting of shareholders and neither the management nor the supervisory board has taken the necessary steps so that the general meeting of shareholders could be held within six weeks after the request.

Also, the agenda for a general meeting of shareholders shall include such items requested by one or more shareholders representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our Articles do not state such lower percentage. Requests must be made in writing and received by the management board at least 60 days before the day of the convocation of the meeting. In accordance with the DCGC, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy, the management board may invoke a response time of a maximum of 180 days from the moment the management board is informed by one or more shareholders of their intention to put an item on the agenda to the day of the general meeting of shareholders at which the item is to be considered. Next to the 180 days response time under the DCGC, as per May 1, 2021, a bill allowing the management board of a Dutch listed company a 250 days statutory response time took effect in the Netherlands. This response time may be invoked if (i) shareholders representing 3% of the issued share capital, request the board to put a proposal on the agenda of the general meeting to (a) appoint, suspend or dismiss members of the management board or supervisory board, or (b) amend the procedures laid down in the articles of association regarding the appointment, dismissal or suspension of a management board or supervisory board member or (ii) an unsolicited public offer is announced or made. Pursuant to the DCGC, the DCGC 180 days response time cannot be invoked if the Company has already invoked the statutory response time for the same item. If the DCGC 180 days response time were to be invoked first, and the statutory response time next, it would be up to the Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*) to rule on any undesirable concurrence between the two mechanisms.

*Delaware.* Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, and has owned such securities for at least one year, may propose a matter for a vote at an annual or special meeting in accordance with those rules. Affimed is not subject to such proxy rules because it is a "foreign private issuer."

#### Action by Written Consent

*The Netherlands.* Under Dutch law, resolutions of the general meeting of shareholders of a Dutch public limited liability company may be adopted in writing without holding a meeting of shareholders, provided that (i) the articles of association allow such action by written consent and (ii) the resolution is adopted unanimously by all shareholders that are entitled to vote. The requirement of unanimity renders the adoption of shareholder resolutions without holding a meeting not feasible for publicly traded companies. Therefore, our Articles do not provide for shareholder action by written consent.

*Delaware.* Although permitted by Delaware law, many publicly listed companies do not permit stockholders of a corporation to take action by written consent.

## Appraisal Rights

*The Netherlands.* The concept of appraisal rights is not known as such under Dutch law.

However, in accordance with the directive 2005/56/EC of the European Parliament and the Council of 26 October 2005 on cross-border mergers of limited liability companies, Dutch law provides that, to the extent that the acquiring company in a cross-border merger is organized under the laws of another EU member state, a shareholder of a Dutch disappearing company who has voted against the cross-border merger may file a claim with the Dutch company for compensation. Such compensation is to be determined by one or more independent experts. The independent experts will take into account any provisions in the articles of association or agreements between the company and shareholders concerning the determination of the fair value of shares and the compensation to be paid to shareholders demanding their shares to be acquired at fair value. If the articles of association or an agreement between the company and the shareholders contains criteria for the unequivocal determination of the fair value of shares and the compensation to be paid to shareholders demanding their shares to be acquired at fair value, no independent experts are required to be appointed. The shares of such shareholder that are subject to such appraisal claim will cease to exist as of the moment of effectiveness of the cross-border merger. If the acquiring company is a company incorporated under the laws of another member state of the European Union or the European Economic Area, the Dutch notary may only issue a declaration stating that the pre-merger formalities have been complied with if no appraisal claim has been filed, the compensation shareholders have been demanding has been paid or the other merging companies have decided that the acquiring company must pay the compensation due to shareholders. The implementation of directive 2019/2121 of the European Parliament and the Council of 27 November 2019 on cross-border conversions, mergers and demergers in Dutch law, which implementation is expected to take place in 2023, will bring certain changes to the (shareholder) rights as set out in this paragraph and will introduce certain rights for, amongst others, shareholders in the context of cross-border conversions and demergers.

*Delaware.* The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

## Shareholder Suits

*The Netherlands.* In the event a third party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in the event that the cause for the liability of a third party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third party in its own name. The DCC provides for the possibility to initiate such actions collectively. A foundation or an association whose objective is to protect the rights of a group of persons having similar interests can institute a collective action if such representative organization meets certain statutory criteria. Until recently a collective action could only result in a declaratory judgment (*verklaring voor recht*). In order to obtain compensation for damages, the foundation or association and the defendant may reach- for instance, on the basis of such declaratory judgment-a settlement. Pursuant to the Dutch Act on the Collective Settlement of Mass Claims (the "WCAM"), a Dutch court may declare the settlement agreement binding upon all the injured parties with an opt-out choice for an individual injured party. However, as of January 1, 2020, new legislation allows Dutch courts to award monetary damages in class action cases. The new legislation encourages parties to explore the options of a collective settlement pending the class action. The new legislation also introduces higher thresholds for class actions and statutory criteria on the basis of which representative organizations can only bring a collective claim before the Dutch courts if they, inter alia, have sufficient expertise on the matter brought before the court, their governance meets certain threshold criteria and are sufficiently funded and transparent concerning their funding. The new legislation also contains stricter rules with regard to the jurisdiction of the Dutch courts. A class action will only be admissible if it has a sufficiently substantive connection with the Netherlands. This will be the case if the majority of the claimants are based in the Netherlands, the defendant is domiciled in the Netherlands or where the unlawful event took place in the Netherlands. Finally, class actions under the new legislation will, as a rule, only apply to injured Dutch parties that have not chosen to opt-out of the class action. Foreign plaintiffs will, in principle, only be bound by the outcome of the class action proceedings if they explicitly opt-in. If a settlement is reached during the proceedings, there is an additional possibility for an injured party to opt-out. This is different than under the WCAM (see above), which does not feature an opt-in for foreign injured parties. If a settlement is declared binding by the Dutch courts pursuant to

the WCAM, all intended beneficiaries are bound by the settlement unless they opt-out. An individual injured party may also itself-institute a civil claim for damages.

*Delaware.* Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

#### Repurchase of Shares

*The Netherlands.* Under Dutch law, when issuing shares, a public company with limited liability such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company with limited liability may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity less the payment required to make the acquisition does not fall below the sum of paid-up and called-up capital and any reserves required by Dutch law or its articles of association and (ii) the company and its subsidiaries would not thereafter hold shares or hold a pledge over shares with an aggregate par value exceeding 50% of its then current issued share capital. Such company may only acquire its own shares if its general meeting of shareholders has granted the management board the authority to effect such acquisitions.

An acquisition of common shares for a consideration must be authorized by our general meeting of shareholders. Such authorization may be granted for a maximum period of 18 months and must specify the number of common shares that may be acquired, the manner in which common shares may be acquired and the price limits within which common shares may be acquired. Authorization is not required for the acquisition of common shares in order to transfer them to our employees. The actual acquisition may only be effected by a resolution of our management board. At the general meeting held on June 22, 2022, the general meeting of shareholders authorized our management board acting with the approval of our supervisory board, for a period of 18 months (until December 22, 2023) to cause the repurchase of common shares by us of up to 10% of our issued share capital, for a price per share not exceeding 110% of the most recent closing price of a common share on any stock exchange where the common shares are listed.

No authorization of the general meeting of shareholders is required if common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee stock purchase plan.

Should we decide to repurchase any of our shares, no votes could be cast at a general meeting of shareholders on the shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depositary receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge.

*Delaware.* Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

d) Anti-Takeover Provisions

*The Netherlands.* Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. We have adopted several provisions that may have the effect of making a takeover of our company more difficult or less attractive, including:

- the staggered four-year terms of our supervisory directors, as a result of which only approximately one-fourth of our supervisory directors will be subject to election in any one year;
- a provision that our managing directors and supervisory directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our outstanding share capital if such removal is not proposed by our supervisory board;
- requirements that certain matters, including an amendment of our Articles, may only be brought to our shareholders for a vote upon a proposal by our management board that has been approved by our supervisory board; and
- a statutory response period. Under Dutch law, the management board can invoke a response period by which a shareholder is prevented from convening a general meeting putting new items on the agenda. As per May 1, 2021, a bill took effect extending the statutory response period from 180 to 250 days.

*Delaware.* In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits “business combinations,” including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. In most cases, such an amendment is not effective until twelve months following its adoption.

e) Inspection of Books and Records

*The Netherlands.* The management board and the supervisory board provide the general meeting of shareholders in good time with all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of us.

*Delaware.* Under the Delaware General Corporation Law, any stockholder may inspect for any proper purpose certain of the corporation’s books and records during the corporation’s usual hours of business.

f) Removal of Directors

*The Netherlands.* Under our Articles, the general meeting of shareholders shall at all times be entitled to suspend or dismiss a member of the management board or supervisory board. The general meeting of shareholders may only adopt a resolution to suspend or dismiss such a member by at least a two-thirds majority of the votes cast, if such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board in which case a simple majority is sufficient.

*Delaware.* Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

g) Pre-emptive Rights

*The Netherlands.* Under Dutch law, upon the issue of common shares, each holder of common shares shall have a preemptive right to acquire such newly issued shares in proportion to the aggregate amount of such holder's common shares, it being understood that this preemptive right shall not apply to (i) the issuance of shares to employees of the company or employees of a group company; and (ii) the issuance of shares against payment in kind.

Under our Articles, if and insofar as the management board is not authorized to limit or exclude pre-emptive rights, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting of shareholders upon proposal of the management board, which proposal has been approved by the supervisory board. The management board, subject to approval of the supervisory board, may also resolve to restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting of shareholders. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting of shareholders to restrict or exclude the preemptive rights or to designate the management board as the authorized body to do so requires a majority of not less than two-thirds of the votes cast, if less than one-half of our issued share capital is represented at the meeting.

At a general meeting held on June 25, 2019, the general meeting of shareholders authorized our management board, subject to the approval of our supervisory board, for a period of five years from the date of the meeting (up to and including June 25, 2024) to restrict or exclude pre-emptive rights accruing to shareholders in connection with the issue of common shares and/or rights to subscribe for common shares in relation to any issuance or granting of rights to subscribe for common shares in the share capital of Affimed, up to the maximum number of common shares that can be issued under the size of the authorized share capital of Affimed as per the date of adoption of such resolution.

*Delaware.* Under the Delaware General Corporation Law, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

h) Dividends

*The Netherlands.* Dutch law provides that dividends may be distributed after adoption of the annual accounts by the general meeting of shareholders from which it appears that such dividend distribution is allowed. Moreover, dividends may be distributed only to the extent the shareholders' equity exceeds the amount of the paid-up and called-up part of the issued share capital and the reserves that must be maintained under the law or the articles of association. Interim dividends may be declared as provided in the articles of association and may be distributed to the extent that the shareholders' equity exceeds the amount of the issued and paid-up and called-up part of the issued share capital and the required legal reserves as described above as apparent from our financial statements.



Under the Articles, the management board may resolve, subject to the approval of the supervisory board, to reserve the profits or part of the profits. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders. We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The management board may resolve, with the approval of the supervisory board, to make interim distributions to the shareholders if an interim statement of assets and liabilities shows that Affimed's shareholders' equity exceeds the sum of the paid-up and called-up part of the capital and the reserves which must be maintained by Dutch law.

Dividends and other distributions shall be made payable no later than thirty days after the date when they were declared, unless the corporate body authorized to declare the dividend determines a different date. Claims to dividends and other distribution not made within five years from the date that such dividends or distributions became payable, shall be forfeited to us (*verjaring*) and shall be carried to the reserves.

*Delaware.* Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

i) Shareholder Vote on Certain Reorganizations

*The Netherlands.* Under Dutch law, the general meeting of shareholders must approve resolutions of the management board relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

*Delaware.* Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

j) Remuneration of Directors

*The Netherlands.* Under Dutch law and our Articles, we must adopt a remuneration policy for our managing directors. Such remuneration policy shall be adopted by the general meeting of shareholders upon the proposal of the supervisory board. The supervisory board determines the remuneration of the management board in accordance with the remuneration policy. A proposal with respect to remuneration schemes in the form of shares or rights to shares must be submitted to the general meeting of shareholders for its approval.

The general meeting may determine the remuneration of supervisory directors. The supervisory directors shall be reimbursed for their expenses.

*Delaware.* Under the Delaware General Corporation Law, the stockholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of executive compensation may be subject to stockholder vote due to the provisions of U.S. federal securities and tax law, as well as exchange requirements.

**11. *Changes in Capital (Item 10.B.10)***

Pursuant to Dutch law, the general meeting of shareholders is authorized to resolve to reduce the issued share capital. Pursuant to our Articles, the general meeting of shareholders, upon proposal of the management board, which proposal must be approved by the supervisory board, may resolve to reduce the issued share capital by (i) reducing the nominal value of shares, or (ii) canceling:

- shares which Affimed holds in its own share capital; or
- all issued shares of a specific class against repayment of the amount paid-up on those shares and, to the extent applicable, repayment of the share premium reserve attached to the relevant class of shares; and against a simultaneous release from the obligation to pay any further calls on the shares to the extent that the shares had not been fully paid-up.

Partial repayment on shares pursuant to a resolution to reduce their nominal value may also be made exclusively on the shares of a specific class.

**12. *Debt Securities (Item 12.A)***

Not applicable.

**13. *Warrants and Rights (Item 12.B)***

Not applicable.

**14. *Other Securities (Item 12.C)***

Not applicable.

**15. *American Depositary Shares (Items 12.D.1 and 12.D.2)***

Not applicable.

## COLLABORATION AGREEMENT

This **COLLABORATION AGREEMENT** (this “*Agreement*”), made as of November 1, 2022 (the “*Effective Date*”), is by and between **AFFIMED GMBH**, a German corporation (“*Affimed*”), having a primary place of business at Im Neuenheimer Feld 582, 69120 Heidelberg, Germany, and **ARTIVA BIOTHERAPEUTICS, INC.**, a Delaware corporation (“*Artiva*”), having a primary place of business at 5505 Morehouse Drive, Suite 100, San Diego, CA 92121, USA. Affimed and Artiva are each referred to herein individually as a “*Party*” and collectively the “*Parties*”.

## RECITALS

**WHEREAS**, Affimed owns or controls the Affimed Product (as defined below), and is developing the Affimed Product for the treatment of certain tumor types;

**WHEREAS**, Artiva owns or controls the Artiva Product (as defined below), and is developing the Artiva Product for the treatment of certain tumor types;

**WHEREAS**, Affimed and Artiva entered into that certain Strategic Collaboration Agreement, dated as of November 5, 2020, and as amended on October 18, 2021 (the “*Prior Collaboration Agreement*”), pursuant to which the Parties conducted preclinical evaluation of certain combination therapies comprising Affimed’s proprietary drug candidates and the Artiva Product;

**WHEREAS**, Affimed and Artiva desire to further collaborate to develop a combination therapy comprising the Affimed Product and the Artiva Product and to facilitate commercialization of the Affimed Product and the Artiva Product by the respective Party for use as part of such combination therapy, as more fully described herein.

**NOW, THEREFORE**, in consideration of the premises and of the following mutual promises, covenants and conditions, the sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, mutually agree as follows:

**1. DEFINITIONS.**

As used in this Agreement, the following capitalized terms shall have the following meanings:

**1.1** “*Accounting Standards*” means the United States Generally Accepted Accounting Principles, consistently applied throughout the organization of a Party, person, corporation, partnership or other entity.

**1.2** “*Affiliate*” means, with respect to a particular Party or entity, any other entity that controls, is controlled by or is under common control with such Party or entity. For the purposes of this Section 1.2, the word “*control*” (including, with correlative meaning, the terms “*controlled by*” or “*under the common control with*”) means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of such Party or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such Party or entity, or by contract or otherwise.

1.3 “**Affirmed Background Know-How**” means any and all Know-How Controlled by Affirmed or its Affiliates as of the Effective Date or during the Term that [\*\*\*\*\*].

1.4 “**Affirmed Background Patents**” means any and all Patents Controlled by Affirmed or its Affiliates as of the Effective Date or during the Term in the Territory that Cover [\*\*\*\*\*]. The Affirmed Background Patents existing as of the Effective Date are set forth in Exhibit 1.4.

1.5 “**Affirmed Background Technology**” means Affirmed Background Patents and Affirmed Background Know-How.

1.6 “**Affirmed Indemnitees**” has the meaning set forth in Section 14.2.

1.7 “**Affirmed Inventions**” has the meaning set forth in Section 10.1(b)(ii).

1.8 “**Affirmed Patents**” has the meaning set forth in Section 10.2(a).

1.9 “**Affirmed Product**” means the product described in Exhibit 1.9, referred to by Affirmed as AFM13.

1.10 “**Affirmed Product Clinical Data**” means [\*\*\*\*\*].

1.11 “**Agreed BD Disclosures**” has the meaning set forth in Section 3.1(b).

1.12 “**Agreed Disclosures**” has the meaning set forth in Section 3.1(b).

1.13 “**Agreed IR Disclosures**” has the meaning set forth in Section 3.1(b).

1.14 “**Agreed Value**” has the meaning set forth in Section 9.2(c).

1.15 “**Agreement Payments**” has the meaning set forth in Section 9.2(a).

1.16 “**Agreement Payments Term**” means, on a country-by-country basis, the period starting on the First Commercial Sale of any In-Scope Artiva Sale or In-Scope Affirmed Sale in such country and ending on the earlier of (A) the launch of a Biosimilar Product for the Artiva Product or Affirmed Product in the Territory and (B) the later of (i) expiration of the last-to-expire Joint Collaboration Patent in such country, and (ii) expiration of regulatory data exclusivity for either the Artiva Product or Affirmed Product in such country

1.17 “**Alliance Manager**” has the meaning set forth in Section 3.6.

1.18 “**APAC Countries**” means the following countries: China (including Hong Kong and Macau), Japan, Mongolia, North Korea, South Korea, Taiwan, Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Timor-Leste, Vietnam, Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka, Australia and New Zealand.

1.19 “**Applicable Laws**” means all federal, state, local, national, regional, supranational, and multinational statutes, laws, rules, regulations and orders applicable to a Party’s performance in connection with this Agreement, including all relevant data protection and privacy laws and

regulations, cGMP, GCP, applicable guidelines of the ICH (including ICH Topic E8 (General Considerations for Clinical Studies)), the FD&C Act, as well as all relevant antitrust/competition laws (each to the extent applicable to a Party's performance in connection with this Agreement).

**1.20** “*Artiva Background Know-How*” means any and all Know-How Controlled by Artiva or its Affiliates as of the Effective Date or during the Term [\*\*\*\*\*].

**1.21** “*Artiva Background Patents*” means any and all Patents Controlled by Artiva or its Affiliates as of the Effective Date or during the Term [\*\*\*\*\*].

**1.22** “*Artiva Background Technology*” means Artiva Background Patents and Artiva Background Know-How.

**1.23** “*Artiva Indemnitees*” has the meaning set forth in Section 14.1.

**1.24** “*Artiva Product*” means the product described in Exhibit 1.24, referred to by Artiva as AB-101.

**1.25** “*Artiva Product Clinical Data*” means [\*\*\*\*\*].

**1.26** “*Artiva Product Inventions*” has the meaning set forth in Section 10.1(b)(i).

**1.27** “*Artiva Product Patents*” has the meaning set forth in Section 10.2(a).

**1.28** “*Bankruptcy Code*” has the meaning set forth in Section 15.3.

**1.29** “*Bankruptcy Event*” has the meaning set forth in Section 15.3.

**1.30** “*Biosimilar Product*” means, with respect to a particular Product that has received Regulatory Approval for a particular Indication in a country or jurisdiction in the Territory and is being marketed and sold by a Party or any of its Affiliates or licensees in the applicable country, a biologic product that [\*\*\*\*\*].

**1.31** “*Business Day*” means a day that is not a Saturday, Sunday or a day on which commercial banking institutions in California, USA or Germany are authorized or required by Applicable Law to remain closed.

**1.32** “*Buy Down Amount*” means [\*\*\*\*\*].

**1.33** “*Calendar Quarter*” means a period of three (3) calendar months commencing on January 1 (Q1), April 1 (Q2), July 1 (Q3) or October 1 (Q4), except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

**1.34** “*Calendar Year*” means a period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date

occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.35 “**CD30**” means the target known as Cluster of Differentiation 30, also referred to as TNFRSF8.

1.36 “**cGMP**” means the current good manufacturing practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Products.

1.37 “**Change of Control**” means, with respect to a Party, that: (a) any Third Party (or group of Third Parties acting in concert) acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party (or group of Third Parties acting in concert) in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which results in stockholders or equity holders of such Party immediately prior to such transaction, no longer owning at least fifty (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party’s consolidated assets taken as a whole, through one or more related transactions.

1.38 “**Change of Control Group**” means, with respect to a Party, the Third Party acquirer of, or successor to, such Party in connection with a Change of Control of such Party, together with all of the Affiliates of such Third Party acquirer or successor, in each case, that are not such Party or Affiliates of such Party immediately prior to the closing of such Change of Control.

1.39 “**Clinical Demand Plan**” has the meaning set forth in Section 8.1(a).

1.40 “**Clinical Trial**” means a Phase I Clinical Trial, Phase II Clinical Trial, Pivotal/Registrational Trial, or Phase III Clinical Trial, or any other trial in which any product is administered to a human subject. For clarity, Clinical Trial includes any confirmatory studies that may be required by the FDA in connection with FDA’s accelerated approval.

1.41 “**CMC**” means chemistry, manufacturing and controls.

1.42 “**Combination Therapy**” means the combination therapy of the Artiva Product and the Affimed Product, [\*\*\*\*\*].

1.43 “**Combination Therapy Clinical Data**” means all data (including raw data) and results generated under any Combination Therapy Trial, including in each case all Artiva Product Clinical Data and Affimed Product Clinical Data, but excluding all Personal Information for which a valid patient consent permitting the sharing of such information for the particular purpose has not been obtained.

1.44 “**Combination Therapy Promotion Plan**” has the meaning set forth in Section 7.2(a).

1.45 “**Combination Therapy Trial**” means each Clinical Trial designed to evaluate the Combination Therapy as agreed by the Parties under this Agreement. For clarity, Combination Therapy Trial includes any Confirmatory Combination Therapy Trial, unless otherwise specified in this Agreement.

1.46 “**Commercialize**” or “**Commercialization**” means, with respect to a Product, activities directed to the preparation for sale or sale of such Product, including activities related to marketing, promoting, detailing, distributing, importing, exporting, launching, selling or offering to sell, or seeking to obtain reimbursement for, such Product, whether before or after Regulatory Approval for the Combination Therapy has been obtained.

1.47 “**Commercially Reasonable Efforts**” means, with respect to a Party performing activities under this Agreement, those efforts and resources [\*\*\*\*\*].

1.48 “**Committee**” means the JEC, JSC, JCC, JDC or any sub-committee established by the JSC, as applicable.

1.49 “**Competing Product**” has the meaning set forth in Section 4.3(e).

1.50 “**Confidential Information**” has the meaning set forth in Section 11.1.

1.51 “**Confirmatory Combination Therapy Trial**” means a confirmatory Clinical Trial (or portion of a Clinical Trial, as described below) required by the FDA as a condition for granting accelerated approval under 21 C.F.R. §601 Subpart E for the Combination Therapy in a particular Indication, whereby such confirmatory Clinical Trial is required for the Combination Therapy to satisfy post-marketing requirements for Regulatory Approval from the FDA, and failure to satisfy such post-marketing requirements may cause the FDA to withdraw its prior accelerated approval. For the sake of clarity, a Confirmatory Combination Therapy Trial may be an extension to an ongoing pre-registrational Combination Therapy Trial for accelerated approval.

1.52 “**Confirmatory Combination Therapy Trial Activities**” means the activities in a Confirmatory Combination Therapy Trial required by the FDA as a condition for accelerated approval of the Combination Therapy in a particular Indication [\*\*\*\*\*].

1.53 “**Confirmatory Combination Therapy Trial Budget**” means a budget specifically for costs of performing the Confirmatory Combination Therapy Trial Activities, as mutually agreed by the Parties.

1.54 “**Control**” or “**Controlled**” means (a) with respect to Patents or Know-How, the ownership of or possession by a Party of the ability to use, practice, license or otherwise exploit such Patents or Know-How as provided herein (without taking into account any rights granted under Patents or Know-How by one Party to the other Party pursuant to this Agreement) without violating the terms of any agreement or arrangement between such Party and any Third Party pursuant to which such Patents or Know-How were licensed, acquired or generated and (b) with respect to proprietary materials, the ownership of or possession by a Party of the ability to use,



supply to the other Party or otherwise exploit such proprietary materials as provided herein (without taking into account any rights granted to materials by one Party to the other Party pursuant to this Agreement) without violating the terms of any agreement or arrangement between such Party and any Third Party, pursuant to which such proprietary materials were acquired or generated. To the extent the use, practice, license, supply to the other Party or other exploitation of any Patents, Know-How or proprietary materials requires any payments to Third Parties, such Patents, Know-How or proprietary materials shall only be deemed "Controlled" by such Party if they have been licensed, acquired or generated (i) before the Effective Date, or (ii) after the Effective Date, but in case of (ii) only upon the mutual agreement of the Parties (including on the bearing of respective costs) which shall, in case of any Patents, Know-How or proprietary materials which are necessary for the performance of either Parties' activities or responsibilities under the Development Plan or this Agreement, not be unreasonably withheld. In the event a Change of Control of a Party after the Effective Date, any Patents, Know-How or materials owned or licensed by any of the Change of Control Group members shall not be deemed "Controlled" by such Party except to the extent such Patent, Know-How or material is also Controlled prior to such transaction by such Party or its Affiliate immediately prior to the closing of such Change of Control.

**1.55** "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent, that, in the absence of ownership of or a license under such Patent, the manufacture, use, sale, offer for sale, or importation of such subject matter would infringe one or more claims of such Patent, or, as to a pending claim included in such Patent, the manufacture, use, sale, offer for sale, or importation of such subject matter would infringe such Patent if such pending claim were to issue in an issued patent.

**1.56** "**Debarment**" or "**Debarred**" means (a) being debarred, or being subject to a pending debarment, pursuant to section 306 of the FD&C Act, 21 U.S.C. § 335a, (b) being listed by any federal or state agencies as excluded, debarred, suspended or otherwise made ineligible to participate in federal or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or being subject to any pending process by which any such listing, exclusion, debarment, suspension or other ineligibility could occur, (c) being disqualified by any foreign government or regulatory agency from performing specific services, or being subject to a pending disqualification proceeding or (d) being convicted of or pleading nolo contendere to a criminal offense related to the provision of healthcare items or services or being subject to any pending criminal action related to the provision of healthcare items or services.

**1.57** "**Demand Projections**" has the meaning set forth in Section 8.1(a).

**1.58** "**Develop**" or "**Development**" means, with respect to a Product or the Combination Therapy, as applicable, research, preclinical development, clinical development, and regulatory activities with respect to such Product or Combination Therapy, including test method development and stability testing, design, compatibility testing, toxicology, animal efficacy studies, formulation, quality assurance and quality control development, statistical analysis, clinical studies (including Clinical Trials, Combination Therapy Trials, the Confirmatory Combination Therapy Trial and any Confirmatory Combination Therapy Trial Activities), regulatory affairs, Regulatory Approval (including the preparation and submission of applications

for such Regulatory Approval) and registration, manufacturing development, packaging development and manufacturing and development documentation efforts in support of development activities anywhere in the world, whether before or after Regulatory Approval for such Product or Combination Therapy has been obtained.

1.59 “**Development Budget**” means [\*\*\*\*\*].

1.60 “**Development Plan**” has the meaning set forth in Section 5.1(a).

1.61 “**Disclosing Party**” has the meaning set forth in Section 11.2(a).

1.62 “**Dispute**” has the meaning set forth in Section 17.1.

1.63 “**EMA**” means the European Medicines Agency and any successor agency thereto.

1.64 “**EU**” means, at any given time during the Term, the then-current member states of the European Union.

1.65 “**Europe**” means, for purposes of this Agreement, the EU and United Kingdom.

1.66 “**Executive Officers**” means the Chief Executive Officer, Chief Operating Officer and Chief Legal Officer of Artiva and Chief Executive Officer, Chief Business Officer, Chief Financial Officer, Chief Operating Officer, Chief Medical Officer and Chief Scientific Officer of Affimed.

1.67 “**FD&C Act**” means the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time, any successor legislation and any corresponding foreign laws, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.68 “**FDA**” means the U.S. Food & Drug Administration and any successor agency thereto.

1.69 “**Field**” means any and all uses in humans or animals.

1.70 “**First Commercial Sale**” means, with respect to any sales of a Product in the Field in a particular country or jurisdiction in the Territory, the first arm’s length commercial sale of such Product for monetary value by a Party or any of its Affiliates or licensees of the Product to a Third Party for end use or consumption by the general public in such country or jurisdiction after the applicable Regulatory Authority in such country or jurisdiction has granted Regulatory Approval of the Combination Therapy (whereas, for clarity, the First Commercial Sale may occur before pricing or reimbursement approvals have been granted); *provided* that the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or licensee for resale; and (b) compassionate use or named patient sales.

1.71 “**FTE**” means the equivalent of the work of a full-time individual for a twelve (12) month period (consisting of a total of [\*\*\*\*\*] hours per year).

**1.72** “*FTE Costs*” means, for any period, the FTE Rate multiplied by the number of FTEs in such period utilized by a Party or its Affiliates arising out of or relating to the performance of the Confirmatory Combination Therapy Trial Activities. FTEs will be pro-rated on a daily basis if necessary.

**1.73** “*FTE Rate*” means [\*\*\*\*\*] per year, subject to adjustments on an annual basis as of January 1 of each year, beginning in 2024, by factors which reflect (i) with respect to FTEs located in the US, any change in the applicable employment cost index, as reported by the U.S. Bureau of Labor Statistics, and (ii) with respect to FTEs located in the EU, any change in the European Union Labour Cost Index (LCI) as reported by Eurostat, in each case (i) and (ii) for January 1 of such year when compared to the comparable statistics for January 1 of the preceding year.

**1.74** “*GCC*” means GC Cell Corporation, and any successor thereto.

**1.75** “*GCP*” means the Good Clinical Practices officially published by EMA, FDA and the ICH that may be in effect from time to time and are applicable to the testing of the Products.

**1.76** “*Healthcare Laws*” means Applicable Laws related to any arrangement involving any items or services paid for by federal health care programs, commercial insurance and/or any drug approved or cleared by FDA,, including, without limitation the FD&Act (21 U.S.C. §§ 301 et seq.), the U.S. federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and its implementing regulations, the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the federal False Statements Law (42 U.S.C. § 1320a-7b(a)), the Civil Monetary Penalties Law (42 U.S.C. §1320a-7a), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. §§286 and 287, the exclusions law (42 U.S.C. §1320a-7), and all other government funded or sponsored healthcare programs, the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the laws governing the U.S. Medicare Program (Title XVIII of the U.S. Social Security Act) including Medicare price reporting (42 U.S.C. § 1395w-3a), the U.S. Medicaid Program (Title XIX of the U.S. Social Security Act) including the collection and reporting requirements and the processing of any applicable rebate, chargeback or adjustment thereunder and under any state supplemental rebate program and the U.S. 340B drug pricing program (42 U.S.C. § 256b), and any state laws or foreign equivalents analogous to any of the foregoing.

**1.77** “*ICF*” has the meaning set forth in Section 5.6.

**1.78** “*ICH*” means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

**1.79** “*IL-2 Product*” means the interleukin 2 cytokine in the form of Proleukin (aldesleukim) to be supplied by Artiva to Affirmed for use in the Combination Therapy Trials under this Agreement.

**1.80** “*Innate Cell Engager Technology*” means any bi-, tri- or multi-specific, engineered antibody construct, designed to engage innate immune cells (e.g., NK Cells) via innate immune cell specific cell surface receptors (e.g., CD16A) and to induce thereby the killing of specifically targeted cancer cells.

**1.81** “*In-Scope Affirmed Adjusted Revenue*” means the definition of “In-Scope Artiva Adjusted Revenue” as applied to sales of the Affirmed Product, *mutatis mutandis*.

**1.82** “*In-Scope Affirmed Sales*” means any sales of the Affirmed Product in the Territory generated by prescription of the Combination Therapy as determined by tracking of sales pursuant to Section 9.2(a). [\*\*\*\*\*].

**1.83** “*In-Scope Artiva Adjusted Revenue*” means the gross amounts invoiced by Artiva and its Affiliates and licensees of the Artiva Product (each, a “*Selling Party*”) to Third Party customers only for In-Scope Artiva Sales, less the following deductions actually incurred, allowed, taken, paid, accrued or allocated with respect to such In-Scope Artiva Sales for:

- (a) [\*\*\*\*\*];
- (b) [\*\*\*\*\*];
- (c) [\*\*\*\*\*]; and
- (d) [\*\*\*\*\*].

All such deductions shall be determined in accordance with the Selling Party’s Accounting Standards. In no event shall any particular amount identified above be deducted more than once in calculating In-Scope Artiva Adjusted Revenue (*i.e.*, no “double counting” of deductions).

In-Scope Artiva Adjusted Revenue shall not include transfers or dispositions of the Artiva Product in connection with the Combination Therapy for charitable, promotional, pre-clinical, clinical, regulatory, or governmental purposes, to the extent provided without charge or sold for no more than the manufacturing costs thereof. In-Scope Artiva Adjusted Revenue shall include the amount or fair market value of all consideration received by the Selling Party in respect of such Artiva Product, whether such consideration is in cash, payment in kind, exchange or other form. In-Scope Artiva Adjusted Revenue shall not include sales between or among the Selling Parties, but shall include the subsequent re-sales to a Third Party.

**1.84** “*In-Scope Artiva Sales*” means any sales of the Artiva Product in the Territory generated by prescription of the Combination Therapy as determined by tracking of sales pursuant to Section 9.2(a). [\*\*\*\*\*].

**1.85** “*In-Scope Adjusted Revenue*” means either the In-Scope Artiva Adjusted Revenue or the In-Scope Affirmed Adjusted Revenue, as applicable.

**1.86** “*IND*” means an investigational new drug application, clinical trial application, clinical trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to commence human clinical trials in such jurisdiction, including any such application filed with the FDA as described in 21 C.F.R. §312.

**1.87** “*Indemnitee*” has the meaning set forth in Section 14.3.

**1.88** “*Indemnitor*” has the meaning set forth in Section 14.3.

1.89 “**Indication**” means a human disease, disorder or medical condition that is [\*\*\*\*\*].

1.90 “**Infringement**” has the meaning set forth in Section 10.3(a).

1.91 “**Initial Territory**” has the meaning set forth in Section 1.141.

1.92 “**Inventions**” means all inventions and discoveries, whether or not patentable, which are made, conceived, or first reduced to practice by or on behalf of a Party or by or on behalf of the Parties together in the performance or as a result of the Combination Therapy Trials or activities under the Development Plan.

1.93 “**Joint Background Know-How**” means the Know-How within or comprising the Joint IP (as defined in the Prior Collaboration Agreement).

1.94 “**Joint Background Patents**” means the Joint Patent Rights (as defined in the Prior Collaboration Agreement). The Joint Background Patents existing as of the Effective Date are set forth in Exhibit 1.94.

1.95 “**Joint Collaboration Inventions**” has the meaning set forth in Section 10.1(b)(iii).

1.96 “**Joint Collaboration Patents**” has the meaning set forth in Section 10.1(b)(iii).

1.97 “**Joint Commercialization Committee**” or “**JCC**” has the meaning set forth in Section 3.3(a).

1.98 “**Joint Executive Committee**” or “**JEC**” has the meaning set forth in Section 3.1.

1.99 “**Joint Patents**” means Joint Background Patents and Joint Collaboration Patents.

1.100 “**Joint Steering Committee**” or “**JSC**” has the meaning set forth in Section 3.2(a).

1.101 “**Joint Technology**” means Joint Background Know-How, Joint Collaboration Inventions and Joint Patents.

1.102 “**Know-How**” means any non-public invention, innovation, improvement, development, discovery, computer program, model, algorithm, device, trade secret, method, know-how, formulation, formula, process, technique, information, results, or data, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, but excluding any Patents.

1.103 “**Later Imposed Withholding**” has the meaning set forth in Section 9.4(b).

1.104 “**Losses**” has the meaning set forth in Section 14.1.

1.105 “**Manufacture**”, “**Manufactured**” or “**Manufacturing**” means all stages of the manufacture of a Product (whether for commercial or clinical purposes), including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal,

labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

**1.106** “*Materials*” has the meaning set forth in Section 5.11(a).

**1.107** “*MDACC Study*” has the meaning set forth in Section 4.3(b).

**1.108** “*NK Cell*” means natural killer cell.

**1.109** “*Non-Program Inventions*” has the meaning set forth in Section 10.1(c).

**1.110** “*Option Territory*” means any of the following groups of countries or jurisdictions, in all cases excluding the Initial Territory and all APAC Countries: (a) Europe, (b) Latin America, (c) North America, (d) Middle East, (e) Africa, and (f) countries and jurisdictions outside of the countries and jurisdictions in clauses (a) through (e); [\*\*\*\*\*].

**1.111** “*Out-of-Pocket Expenses*” means reasonable and documented amounts paid by or on account of a Party to any Third Party, including vendors, consultants, or contractors, for services reasonably necessary and identifiable to the performance of the Confirmatory Combination Therapy Trial Activities. For clarity, “*Out-of-Pocket Expenses*” does not include payments for a Party’s or its Affiliates’ employee salaries, benefits, utilities, travel expenses, general office supplies, insurance, information technology or capital expenditures.

**1.112** “*Patents*” means (a) any and all patents, certificates of invention, applications for certificates of invention, priority patent filings, and patent applications, and (b) any and all renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, supplementary protection certificates, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

**1.113** “*Patent Budget*” has the meaning set forth in Section 10.2(b)(i).

**1.114** “*Paying Party*” has the meaning set forth in Section 9.4(b)(i).

**1.115** “*Personal Information*” means, in addition to any definition for any similar term (e.g., “personal data” or “personal health information” or “personally identifiable information” or “PII”) provided by Applicable Laws, or by either Party in any of its own privacy policies, notices or contracts, all information that identifies, could be used to identify or is otherwise associated with an individual person, whether or not such information is directly associated with an identified individual person.

**1.116** “*Pharmacovigilance Agreement*” means that certain pharmacovigilance agreement being entered into by the Parties pursuant to Section 6.4, as amended from time to time.

**1.117** “*Phase I Clinical Trial*” means a human clinical trial that would satisfy the requirements of 21 C.F.R. §312.21(a) (or the comparable requirements of the relevant Regulatory Authority in a country other than the Initial Territory, as applicable).

**1.118** “*Phase II Clinical Trial*” means a human clinical trial would satisfy the requirements of 21 C.F.R. §312.21(b) (or the comparable requirements of the relevant Regulatory Authority in a country other than the Initial Territory, as applicable).

**1.119** “*Phase III Clinical Trial*” means a human clinical trial would satisfy the requirements of 21 C.F.R. §312.21(c) (or the comparable requirements of the relevant Regulatory Authority in a country other than the Initial Territory, as applicable).

**1.120** “*Pivotal/Registrational Trial*” means either (a) a human clinical trial, the principal purpose of which is to demonstrate clinically and statistically the efficacy and safety of a product for one (1) or more Indication(s) in order to obtain Regulatory Approval of such product for such Indication(s), as further defined in 21 C.F.R. §312.21 (or the comparable regulations of the relevant Regulatory Authority in a country other than the Initial Territory, as applicable) or (b) a human clinical trial of a product on a sufficient number of subjects that satisfies both clauses (i) and (ii): (i) such trial is designed to establish that a product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such product; and (ii) such trial is a registrational trial that, if successful, would be sufficient to support the filing of an application for Regulatory Approval for such product in the United States or the EU, as evidenced by (A) an agreement with or statement from the FDA or the EMA on a ‘Special Protocol Assessment’ or equivalent, or (B) other guidance or minutes issued by the FDA or EMA, for such registrational trial, in each case (of (a) and (b)), regardless of whether the sponsor of such trial identifies, characterizes or refers to such trial as a “Phase 3,” “Phase 2b” or “Phase 2b/3” trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context.

**1.121** “*Prior Collaboration Agreement*” has the meaning set forth in the recitals.

**1.122** “*Products*” means, collectively, the Artiva Product and the Affimed Product. A “*Product*” means either the Artiva Product or the Affimed Product, as applicable.

**1.123** “*Promote*” or “*Promotion*” means, with respect to the Combination Therapy, activities directed to the marketing, promoting or detailing such Combination Therapy in any Indication in the Field in the Territory following Regulatory Approval for the Combination Therapy in such Indication.

**1.124** “*Promotional Materials*” means all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave items, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings, and broadcast advertisements, in each case, created by a Party or on its behalf and used or intended for use by or on behalf of such Party in connection with Commercialization of its Product or the Promotion of the Combination Therapy in the Field in the Territory.

**1.125** “*Prosecution and Maintenance*” means, with regard to a given Patent, the preparation, filing, prosecution and maintenance of such Patent, as well as any ex parte and inter partes proceedings, including reexaminations, reissues, applications for patent term extensions,



interferences, derivation proceedings, post grant review proceedings, oppositions, litigations, arbitrations and other similar proceedings with respect to such Patent.

1.126 “**Protocol**” has the meaning set forth in Section 5.5.

1.127 “**Publication**” has the meaning set forth in Section 12.2(b).

1.128 “**Quality Agreement**” has the meaning set forth in Section 5.13.

1.129 [\*\*\*\*\*].

1.130 “**Receiving Party**” has the meaning set forth in Section 11.2(a).

1.131 “**Recipient Party**” has the meaning set forth in Section 9.4(b)(i).

1.132 “**Regulatory Approvals**” means any and all permissions (other than the Manufacturing, pricing and reimbursement approvals) required to be obtained from the relevant Regulatory Authorities and any other competent governmental authority for the Commercialization of any Product or the Promotion of the Combination Therapy in a given country or regulatory jurisdiction in the Territory.

1.133 “**Regulatory Authority**” means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any country or territory of the world with jurisdiction over the Development, Manufacture or Commercialization of a Product or Development or Promotion of the Combination Therapy, including the FDA and the EMA.

1.134 “**Regulatory Materials**” means regulatory applications, submissions, notifications, correspondences, registrations, INDs, Regulatory Approvals or other filings made to or with, or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Develop, Manufacture or Commercialize a Product or Develop or Promote the Combination Therapy in a particular country or regulatory jurisdiction in the Territory.

1.135 “**Related Agreements**” means the Pharmacovigilance Agreement and the Quality Agreement.

1.136 “**SAEs**” means serious adverse events.

1.137 “**Samples**” means biological samples, such as urine, blood and tissue samples, collected from patients participating in a Combination Therapy Trial.

1.138 “**SEC**” means the U.S. Securities and Exchange Commission and any successor agency thereto.

1.139 “**Selling Party**” has the meaning set forth in Section 1.79.

1.140 “**Term**” has the meaning set forth in Section 15.1.

1.141 “**Territory**” means the United States and its territories and possessions (the “**Initial Territory**”) and each Option Territory (if any) that the Parties agree to include in rights granted under this Agreement in accordance with Section 2.2.

1.142 “**Third Party**” means any person or entity other than Affimed, Artiva or their respective Affiliates.

1.143 “**Third Party Claim**” has the meaning set forth in Section 14.1.

1.144 “**Unanimous Matter**” has the meaning set forth in Section 3.5(a).

1.145 “**VAT**” means any value added, sales, goods, services, turnover, consumption, use or similar tax, including value added tax as may be levied by any member state of the EU on the basis of Directive 2006/112/EC (as amended from time to time) and comparable taxes under the laws of any other jurisdiction outside the EU (for the avoidance of doubt, excluding income or net profit taxes or franchise taxes of any kind).

## 2. OVERVIEW; TERRITORY EXPANSION

2.1 **Overview.** Subject to the terms and conditions of this Agreement, the Parties shall collaborate to conduct Development of the Combination Therapy in the Field in the Territory, and the Parties will Commercialize their respective Products for the Combination Therapy in the Field in the Territory. To the extent mutually agreed in the Development Plan, certain Development activities may be conducted outside the Territory (but only for the purpose of seeking Regulatory Approval and Commercialization in the Territory), and all references in this Agreement to Development in the Territory shall be construed accordingly.

2.2 **Territory Expansion.** At any time during the Term, upon receipt of a written notice from Affimed by Artiva requesting expansion of the Territory to include any of the Option Territory(ies), the Parties shall discuss in good faith any amendment to this Agreement as necessary to include such Option Territory(ies) in the Territory, including any additional Clinical Trials as may be required by the applicable Regulatory Authority in such Option Territory(ies); *provided* that such amendment shall not materially change any payment obligations of either Party to the other Party under this Agreement except as otherwise agreed in writing by the Parties.

## 3. GOVERNANCE

### 3.1 Joint Executive Committee.

(a) Within [\*\*\*\*\*] days after the Effective Date, the Parties shall establish a joint executive committee (the “**Joint Executive Committee**” or “**JEC**”). The JEC shall consist of (i) the Chief Executive Officer and (ii) the Chief Business Officer or Chief Operating Officer of either Party. The JEC shall (a) discuss and coordinate on corporate and strategic topics relating to the Combination Therapy that require alignment between the Parties, (b) review, discuss and resolve any matter within the decision-making authority of the JSC or the JCC on which the JSC or the JCC cannot reach consensus pursuant to Section 3.5(a), and (c) agree and coordinate on timing and venue of all public disclosures related to the Combination Therapy, including release of Combination Therapy Clinical Data, descriptions of the Combination Therapy, publication

strategies pertaining to the Combination Therapy (e.g., press releases or corporate presentations), and any required disclosures and filings a Party may be obligated to make under Applicable Law with the SEC or other similar governmental authorities, provided that the foregoing shall not limit each Party's right to make such required disclosures and filings in accordance with Section 11.3.

(b) Within [\*\*\*\*\*] days after the Effective Date, the Parties shall establish a joint disclosure committee as a subcommittee of the JEC (the "**Joint Disclosure Committee**" or "**JDC**"). The JDC shall consist of the Chief Executive Officer as well as other senior executives and internal and/or external legal counsels of both Parties as each Party deems appropriate, including SEC counsel where relevant. The JDC shall :

(i) review and agree as to the scope of unpublished Combination Therapy Clinical Data that are pre-approved to be disclosed by each Party to (i) *bona fide* potential or actual investors or financial partners (such as agreed and pre-approved disclosures, the "**Agreed IR Disclosures**"), or (ii) *bona fide* potential or actual acquirers, merger partners or business partners (including potential licensing partners) (such as agreed and pre-approved disclosures, the "**Agreed BD Disclosures**", and the Agreed IR Disclosures and Agreed BD Disclosures together the "**Agreed Disclosures**"), in each case of (i) and (ii) in accordance with Section 11.3(e); and

(ii) receive notifications of (and review where applicable) any disclosures to potential or actual investors or financial partners or to potential or actual acquirers, merger partners or business partners (including potential licensing partners) beyond the Agreed Disclosures according to Section 11.3(e).

(c) The JDC shall document its decisions and strategies in a disclosure plan that shall be updated at least on a quarterly basis.

### 3.2 **Joint Steering Committee.**

(a) **Formation.** Within [\*\*\*\*\*] days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"). The JSC shall consist of [\*\*\*\*\*] representatives from each Party, and each representative shall have the requisite experience and seniority to enable such person to make decisions on behalf of the applicable Party with respect to the issues falling within the authority of the JSC. From time to time, each Party may substitute one (1) or more of its representatives to the JSC upon written notice to the other Party.

(b) **Responsibilities of the JSC.** The JSC shall perform the following functions:

(i) oversee, guide and approve the overall strategic direction of the Parties' collaboration with respect to Development of the Combination Therapy (but without modifying or limiting the rights or obligations of either Party as otherwise set forth herein);

(ii) review and approve the Development Plan, including any updates or amendments thereto, in accordance with Section 5.1;

(iii) oversee, review and coordinate the conduct, implementation and progress of the Development activities with respect to the Combination Therapy under this Agreement, as described in the applicable Development Plan;

(iv) review and approve the final ICF according to Section 5.6;

(v) discuss strategy and regulatory pathway for obtaining Regulatory Approval for the Combination Therapy;

(vi) review and approve the Protocols including any updates or amendments thereto;

(vii) consider information provided by either Party pursuant to Section 5.12 with respect to a Third Party subcontractor which that Party wishes to newly involve in the conduct of activities in connection with a Combination Therapy Trial;

(viii) review and coordinate the supply of the Products for the Development of the Combination Therapy under this Agreement in accordance with the Development Plan and Article 8;

(ix) review and approve the contents of the initial publication of the Combination Therapy Clinical Data generated in a Combination Therapy Trial pursuant to Section 12.2(a), in accordance with the guidelines (including timing and venue) agreed by the JEC;

(x) exchange information with respect to each Party's activities with respect to the Development of such Party's Product as relevant to the Development of the Combination Therapy pursuant to this Agreement;

(xi) review on a quarterly basis the Combination Therapy Clinical Data;

(xii) review on a quarterly basis the actual expenditures for the Confirmatory Combination Clinical Trial against the Confirmatory Combination Therapy Trial Budget and discuss any expected overages in accordance with Section 5.4;

(xiii) establish, as appropriate, additional sub-committees responsible for managing specific aspects of the Parties' collaboration as contemplated herein;

(xiv) oversee and supervise any subcommittees the JSC may establish as necessary and resolve issues or dispute elevated to it by any such subcommittee; and

(xv) perform such other functions as are assigned to the JSC in this Agreement, or otherwise delegated to the JSC by the JEC (within the authority of the JEC) or agreed by the Parties in writing.

### 3.3 Joint Commercialization Committee.

(a) **Formation.** Prior to filing of the first application for Regulatory Approval for the Combination Therapy, the Parties shall establish a joint commercialization committee (the

“JCC”). The JCC shall consist of [\*\*\*\*\*] representatives from each Party, and each representative shall have the requisite experience and seniority to enable such person to make decisions on behalf of the applicable Party with respect to the issues falling within the authority of the JCC. From time to time, each Party may substitute one (1) or more of its representatives to the JCC upon written notice to the other Party.

**(b) Responsibilities of JCC.** The JCC shall perform the following functions:

**(i)** oversee and coordinate the overall strategic direction of the Promotion of the Combination Therapy in accordance with Article 7 (but without modifying or limiting the rights or obligations of either Party as otherwise set forth herein);

**(ii)** review and discuss the Combination Therapy Promotion Plan and any material updates or amendments thereto, in accordance with Section 7.2;

**(iii)** review the Promotional Materials for the Combination Therapy generated by Affirmed pursuant to Section 7.3(c)(ii) and, only to the extent the Promotional Materials contain statements relating to the Artiva Product (e.g., relating to its efficacy, safety or use) as a monotherapy or as part of the Combination Therapy (and not the Affirmed Product), approve such statements within such Promotional Materials (but no other aspect of such Promotional Materials such as layout and design), taking into account any guidance and assessments presented by functional representatives of either Party (who may attend the respective JCC meeting in accordance with Section 3.4), *provided that* the review and, if applicable, approval process shall be completed in any event within ten (10) Business Days from the date the Promotional Materials are submitted to the JCC;

**(iv)** review and approve each Party’s use of the other Party’s trademarks, logos, Promotional Materials, trade dress, copyrights, corporate logos, corporate names, visual identity and branding elements, in each case, in connection with the Promotion of the Combination Therapy as set forth in Section 7.3(c)(iv);

**(v)** review and discuss, as necessary, the Demand Projection in accordance with Section 8.1(a), the In-Scope Adjusted Revenue Tracking Methodology as set forth in Section 9.2(a), and the Agreement Payment as set forth in Section 9.2(c);

**(vi)** exchange information with respect to each Party’s activities with respect to the Commercialization of such Party’s Product as relevant and necessary to the commercialization of the Combination Therapy pursuant to this Agreement (at all times to the extent such information exchange is permitted by Applicable Law); and

**(vii)** perform such other functions as are assigned to the JCC in this Agreement, or otherwise delegated to the JCC by the JEC (within the authority of the JEC) or agreed by the Parties in writing.

**3.4 Committee Meetings.** Each of the JDC, JSC and the JCC shall meet at least once [\*\*\*\*\*], either in person or by audio or video conference with the venue of the in-person meetings alternating between locations designated by each Party. For clarity, each Party may call special meetings of the JDC, JSC or the JCC with at least [\*\*\*\*\*] Business Days’ prior written notice, or

a shorter time-period in exigent circumstances, to resolve particular matters requested by such Party that are within the purview of the JDC, JSC or the JCC, respectively. Employees of each Party other than JDC, JSC or JCC representatives may attend meetings of such Committee as non-voting participants. The JEC will meet upon reasonable request of either Party and as reasonably necessary to coordinate public disclosures with respect to the Combination Therapy as described in Section 3.1, either in person or by audio or video conference. Each Party shall bear all travel, lodging, meal and other expenses associated with the attendance of its representatives and other personnel at Committee meetings. The Parties shall alternate in preparing and circulating minutes of each Committee meeting within [\*\*\*\*\*] days after such meeting for the Parties' review and approval. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting and shall document all actions and determinations approved by the applicable Committee at such meeting. The Parties shall promptly discuss any comments on such minutes and finalize the minutes no later than the date of the next Committee meeting.

### 3.5 Decision-Making.

**(a) Committee Decision Making.** All decisions of each Committee shall be made by unanimous vote, with Affimed's representatives collectively having one (1) vote and Artiva's representatives collectively having one (1) vote. No action taken at any meeting of a Committee shall be effective unless a representative of each Party is participating in such meeting. Representatives of each Party on each Committee shall use reasonable efforts to resolve any dispute within the authority of such Committee in good faith, and the Parties shall first attempt to resolve any such dispute in accordance with this Section 3.5, *provided* that:

**(i)** [\*\*\*\*\*].

**(ii)** [\*\*\*\*\*].

**(b)** [\*\*\*\*\*] (each, a "*Unanimous Matter*"), which may only be decided by written agreement of both Parties:

**(i)** expand or add any obligations of Artiva, including any costs incurred by Artiva, beyond what Artiva has otherwise agreed in writing;

**(ii)** amend or change the Development Plan (or the activities under the Development Plan) in a manner that would reasonably be likely to materially change the commercial opportunity of the Artiva Product, where "materially change", for purposes of this Section 3.5(b)(ii), means [\*\*\*\*\*];

**(iii)** amend or change the Development Plan to include additional Indications or remove existing Indications, or to change the Development Budget;

**(iv)** decide any aspect of the Confirmatory Combination Therapy Trial, including the Confirmatory Combination Therapy Trial Budget;

**(v)** decide any aspect of any Protocol, Regulatory Materials or strategy therefor, or make any other decision, in each case to the extent that it relates to the Artiva Product (including as part of the Combination Therapy), including [\*\*\*\*\*];

(vi) approving statements within Promotional Materials solely to the extent they are relating to the Artiva Product (e.g., relating to its efficacy, safety or use) as a monotherapy or as part of the Combination Therapy (and not the Affirmed Product);

(vii) [\*\*\*\*\*];

(viii) [\*\*\*\*\*]; or

(ix) determining or modifying the In-Scope Adjusted Revenue Tracking Methodology, Demand Projections or Clinical Demand Plan, or modifying the Royalty Payments.

The Parties acknowledge and agree that any decision of an Unanimous Matter relating to a Clinical Trial shall be subject to and reflect any requirements of a Regulatory Authority, and that no Party may object to the implementation of a Regulatory Authority's requirements even if these contradict the commercial assumptions and arrangements between the Parties under this Agreement, including the commercial opportunity of the Artiva Product as set out in Section 3.5(b)(ii). For clarity, if the Parties are not able to mutually resolve any disputes or agree on any Unanimous Matter in accordance with the procedures in this Section 3.5(a), either of the Parties may submit such Unanimous Matter for final resolution by arbitration pursuant to Article 17.

(c) **Scope of Authority.** The Committees shall have only such rights, powers and authority as are expressly delegated to them under this Agreement. Notwithstanding any other provision of this Agreement, neither any Committee, [\*\*\*\*\*], shall have the right to: (i) modify or amend this Agreement; (ii) waive compliance with this Agreement; (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; (iv) resolve any dispute between the Parties regarding interpretation of this Agreement; (v) make a decision that is expressly stated to require the mutual written agreement or mutual written consent of the Parties or an amendment to this Agreement; or (vi) require either Party to violate any Applicable Law; for the avoidance of doubt, any reference to "this Agreement" in (i) to (v) shall not be read to include a reference to the Development Plan. Notwithstanding the establishment and existence of the Committees, each Party shall retain the rights, powers and discretion granted to it hereunder, and the JEC or any other Committee shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein.

**3.6 Alliance Managers.** Within [\*\*\*\*\*] days after the Effective Date, each Party shall appoint (and notify the other party of the identity of) a representative of such Party to act as the primary point of contact for the Parties regarding the Development and Promotion of the Combination Therapy under this Agreement (each, an "**Alliance Manager**"). The Alliance Managers shall be responsible for creating and maintaining collaborative, efficient, and responsive communications within and between Affirmed and Artiva. A Party may replace its Alliance Manager upon written notice to the other Party. Each Alliance Manager may attend any Committee meetings held under this Article 3 as a non-voting member and shall bring matters to the attention of the relevant Committee if the Alliance Manager reasonably believes that such matter warrants such attention.

#### 4. LICENSE GRANTS; CLINICAL DATA; EXCLUSIVITY

##### 4.1 License Grant.

(a) **Grant by Artiva.** Subject to the terms of this Agreement, Artiva hereby grants to Affirmed:

(i) an exclusive, non-transferable (except as set forth in Section 18.2), royalty-free license, with no right to sublicense except in accordance with Section 4.1(c), under the Artiva Background Technology, Artiva Product Inventions, Artiva Product Patents and Artiva's interest in Joint Technology, in each case to the extent reasonably necessary or useful for the Development of the Combination Therapy in the Field in the Territory, solely to use the Artiva Product to Develop the Combination Therapy in the Field in the Territory to the extent of activities or responsibilities allocated to Affirmed in accordance with the Development Plan or this Agreement. For clarity, the foregoing license does not include any right to Manufacture or Commercialize the Artiva Product or to Develop the Artiva Product outside the Combination Therapy; and

(ii) a non-exclusive, non-transferable (except as set forth in Section 18.2), royalty-free license, with no right to sublicense except in accordance with Section 4.1(c), under the Artiva Background Technology, Artiva Product Inventions, Artiva Product Patents and Artiva's interest in Joint Technology to the extent reasonably necessary or useful for the Promotion of the Combination Therapy in the Field in the Territory solely to Promote the Combination Therapy in the Field in the Territory.

(b) **Grant by Affirmed.** Subject to the terms of this Agreement, Affirmed hereby grants to Artiva a non-exclusive, non-transferable (except as set forth in Section 18.2), royalty-free license, with no right to sublicense except in accordance with Section 4.1(c), under the Affirmed Background Technology, Affirmed Inventions, Affirmed Patents and Affirmed's interest in Joint Technology, in each case to the extent reasonably necessary or useful for the Development of the Combination Therapy in the Field in the Territory, solely to use the Affirmed Product to Develop the Combination Therapy in the Field in the Territory to the extent of activities or responsibilities allocated to Artiva in accordance with the Development Plan or this Agreement. For clarity, the foregoing license does not include any right to Manufacture or Commercialize the Affirmed Product or to Develop the Affirmed Product outside the Combination Therapy.

(c) **Sublicense.** Neither Party shall have the right to grant sublicenses under the licenses granted to it under Section 4.1(a) or Section 4.1(b), as applicable, except [\*\*\*\*\*]. Any other sublicenses shall be subject to the other Party's express prior written consent in its sole discretion. Each Party shall remain liable to the other Party for the acts and omissions of its sublicensees.

(d) **No Implied Licenses.** For clarity, nothing in this Agreement provides either Party with any rights, title or interest or any license to the other Party's intellectual property except as expressly set forth in this Agreement. Each Party agrees that it shall not, and shall not permit any of its Affiliates, licensees or sublicensees to, practice any Patent or Know-How licensed



to it by the other Party outside the scope of the licenses expressly granted to it under this Agreement.

**4.2 Ownership and Use of Artiva Product Clinical Data, Affirmed Product Clinical Data and Combination Therapy Clinical Data.**

**(a) Ownership.** The Parties shall jointly own all Combination Therapy Clinical Data in equal and undivided shares, except for any Affirmed Product Clinical Data comprised therein which shall be solely owned by Affirmed, and any Artiva Product Clinical Data comprised therein which shall be solely owned by Artiva. Affirmed shall maintain all Combination Therapy Clinical Data in its database and shall grant access to Combination Therapy Clinical Data to Artiva in accordance with Section 5.10. In each case in accordance with and subject to the limitations set forth in this Section 4.2(b) [\*\*\*\*\*].

**(b) Use and disclosure of Unpublished Combination Therapy Clinical Data.** Prior to publication of the Combination Therapy Clinical Data in accordance with Section 12.2, either Party may use and disclose the Combination Therapy Clinical Data solely as follows:

**(i)** Artiva shall be free to use and disclose the Artiva Product Clinical Data for any purpose at its discretion;

**(ii)** Affirmed shall be free to use and disclose the Affirmed Product Clinical Data for any purpose at its discretion;

**(iii)** Affirmed may use and disclose any Combination Therapy Clinical Data to the extent disclosure is required to clinical sites (or Affiliate or Third Party subcontractors in accordance with Section 5.12) in connection with the Combination Therapy Trials;

**(iv)** [\*\*\*\*\*];

**(v)** [\*\*\*\*\*];

**(vi)** [\*\*\*\*\*];

**(vii)** [\*\*\*\*\*];

**(viii)** each Party may disclose the Combination Therapy Clinical Data to the extent such disclosure is required to comply with Applicable Laws (e.g., disclosures to the SEC or other similar governmental authorities) or is in connection with Regulatory Materials or communications with Regulatory Authorities in the Territory regarding the Combination Therapy or Combination Therapy Trials, in each case in accordance with Section 11.3;

**(ix)** each Party may disclose the Combination Therapy Clinical Data to the extent such disclosure is required to Regulatory Authorities in compliance with a Party's policies and procedures relating to pharmacovigilance and adverse event reporting for its Product;

**(x)** [\*\*\*\*\*]

(xi) each Party may disclose the Combination Therapy Clinical Data to the extent such disclosure is expressly permitted under Section 11.3.

Each Party shall implement appropriate technical and organizational measures to ensure compliance with the limitations of use and disclosure of certain Combination Therapy Clinical Data set out in this Section 4.2(b), [\*\*\*\*\*].

(c) **Use After Publication.** Following publication of any portion of the Combination Therapy Clinical Data, each Party shall be free to use such portion of the Combination Therapy Clinical Data for any purpose.

#### 4.3 Exclusivity.

(a) **Mutual Exclusivity Obligations.** During the Term, to the extent permitted under Applicable Law and subject to the terms of this Section 4.3, neither Party nor any of its Affiliates, either internally or through intentionally enabling a Third Party, shall clinically develop or commercialize any product or therapy comprising its Product, [\*\*\*\*\*], in the Field in the Territory for any Indication which is included in the then-applicable Development Plan and for which the Parties have agreed to file an IND, except for the Combination Therapy in accordance with this Agreement.

(b) **Affirmed's Exclusivity Obligations.** During the Term, to the extent permitted under Applicable Law and subject to the terms of this Section 4.3, neither Affirmed nor any of its Affiliates, either internally or through intentionally enabling a Third Party, shall clinically develop or commercialize any product or therapy comprising the Affirmed Product and an NK Cell, [\*\*\*\*\*];

(c) **Artiva's Exclusivity Obligations.** During the Term, to the extent permitted under Applicable Law and subject to the terms of this Section 4.3, neither Artiva nor any of its Affiliates, either internally or through intentionally enabling a Third Party, shall clinically develop or commercialize any product that directly and specifically binds to CD30 (not including pathway effects) without any known off-target binding that is pre-clinically or clinically relevant in the Field in the Territory [\*\*\*\*\*];

(d) **Exceptions.** The exclusivity obligations according to Section 4.3(a) to 4.3(c) shall not apply:

(i) [\*\*\*\*\*];

(ii) [\*\*\*\*\*];

(iii) [\*\*\*\*\*]

(iv) in case of either Party, to support of academic not-for-profit research (excluding, for clarity, clinical research or development), or compassionate use programs, either by providing funding or providing any product, and granting the necessary rights under Patents and Know-How Controlled by the relevant Party or any of its Affiliates in connection therewith.

**5. DEVELOPMENT**

**5.1 Development Plan.**

(a) **Development Plan.** Subject to the terms and conditions of this Agreement, the Parties shall use Commercially Reasonable Efforts to Develop the Combination Therapy in accordance with a written development plan (as may be amended, the “*Development Plan*”). The Development Plan shall set forth (without limitation): (i) the objectives and activities of the Parties with respect to Development of the Combination Therapy; (ii) target Indications for the Combination Therapy [\*\*\*\*\*], Combination Therapy Trials planned for such Indications, key Regulatory Authority meetings, and filing of applications for Regulatory Approval, in each case, including the Parties’ good-faith estimate of relevant timelines therefor; (iii) strategy and regulatory pathway for obtaining Regulatory Approval for the Combination Therapy, including the Parties’ respective roles in the development of the registration dossier and Regulatory Materials for the Combination Therapy and (iv) a mutually agreed Development Budget. [\*\*\*\*\*].

(b) **Amendment to the Development Plan.** The draft Development Plan that is mutually agreed upon by the Parties is attached hereto as Exhibit 5.1(b), and the JSC shall review and approve an initial Development Plan based on such draft at its first meeting after the Effective Date. The JSC shall regularly review the Development Plan and the progress of activities being conducted under the Development Plan. Subject to Section 3.5, the JSC shall update the then-current Development Plan once every Calendar Year, or more or less often as the Parties deem appropriate. If the Parties determine to seek Regulatory Approval for the Combination Therapy in the Initial Territory, and the FDA requires the conduct of a Confirmatory Combination Therapy Trial as a condition for granting accelerated approval under 21 C.F.R. §601 Subpart E for the Combination Therapy in a particular Indication, then the Parties shall update the Development Plan to include the conduct of such Confirmatory Combination Therapy Trial, including the Confirmatory Combination Therapy Trial Budget for the applicable Confirmatory Combination Therapy Trial Activities, to be approved by the JSC. [\*\*\*\*\*] Subject to Section 3.5, the Development Plan as updated or amended shall (i) be in effect upon JSC’s approval of such Development Plan and (ii) supersede the previous Development Plan for the applicable period. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail. [\*\*\*\*\*].

**5.2 Performance.** Each Party shall use Commercially Reasonable Efforts to perform the Development tasks assigned to it under the Development Plan in accordance with the Development Plan, including the timelines specified therein. Each Party shall conduct its activities under the Development Plan in a good scientific manner and in compliance with all Applicable Laws.

**5.3 Allocation of Responsibilities.**

(a) **Affirmed’s Responsibilities.** Affirmed shall control and be primarily responsible for the Development of the Combination Therapy in accordance with this Agreement and the Development Plan. Subject to the terms and conditions of this Agreement and the

oversight of the JSC, Affimed shall (i) act as the sponsor of the Combination Therapy Trials as set forth in Section 6.1(a), and (ii) manage and be primarily responsible for the conduct of the applicable Combination Therapy Trial, including (A) managing the operations of the Combination Therapy Trials in accordance with the applicable Protocol, including overseeing compliance by any subcontractor (including clinical research organizations) engaged by Affimed for the Combination Therapy Trials; and (B) concluding all necessary agreements with Third Party subcontractors (including clinical research organizations) and clinical trial sites and ensuring that these agreements (1) are consistent with the relevant terms of this Agreement, including confidentiality and intellectual property provisions consistent with those set forth in this Agreement, and (2) permit Affimed to audit trial sites for quality assurance, to inspect and copy all data, documentation and work products relating to the Combination Therapy Trials and to share audit results relating to the Combination Therapy Trials with Artiva. Affimed shall perform all Combination Therapy Trials in accordance with this Agreement, the Protocol, and all Applicable Laws, including GCP. Without limiting the generality of the foregoing in this Section 5.3(a), Affimed shall use Commercially Reasonable Efforts to (x) file an IND for the Combination Therapy with the FDA [\*\*\*\*\*]; and (y) dose the first subject in a Phase I Clinical Trial of the Combination Therapy [\*\*\*\*\*]. Affimed shall ensure that all Regulatory Approvals from any Regulatory Authority or ethics committee with jurisdiction over the Combination Therapy Trials are obtained prior to initiating performance of such Combination Therapy Trials.

**(b) Artiva's Responsibilities.** Artiva shall carry out those activities assigned to Artiva pursuant to the Development Plan and, unless otherwise specified, in this Agreement at no cost to Affimed; [\*\*\*\*\*].

**(c) Responsibility Allocation Matrix.** Without limiting the other terms of Articles 5 through 7, Exhibit 5.3(c) sets forth each Party's responsibilities relating to the Development of the Combination Therapy, which, unless expressly provided under this Agreement, may only be amended upon written agreement of the Parties.

**5.4 Development Costs.** Affimed shall be solely responsible for all costs associated with the Development of the Combination Therapy (including, for clarity, all costs associated with all Combination Therapy Trials) in accordance with this Agreement and the Development Plan (including the Development Budget); except that (a) Artiva shall be solely responsible for all costs incurred by Artiva in (i) supplying sufficient quantities of Artiva Products and IL-2 Product pursuant to Article 8, and (ii) performing any activities allocated to Artiva pursuant to Section 5.3(b), and (b) if the FDA requires the conduct of a Confirmatory Combination Therapy Trial as a condition for granting accelerated approval under 21 C.F.R. §601 Subpart E for the Combination Therapy in a particular Indication in the Initial Territory, then each of Affimed and Artiva shall bear fifty percent (50%) of the FTE Costs and Out-of-Pocket Expenses incurred by the Parties for the performance of the Confirmatory Combination Therapy Trial Activities in accordance with Section 9.1, including all direct costs of manufacturing, supplies, equipment and materials and related expenditures incurred by each Party in supplying sufficient quantities of such Party's Product for such Confirmatory Combination Therapy Trial Activities. Except as expressly set

forth in this Section 5.4, Artiva shall not be responsible for any costs associated with the Development of the Combination Therapy. [\*\*\*\*\*].

**5.5 Protocol.** Each Combination Therapy Trial shall be conducted in accordance with a protocol (each, as may be amended, a “*Protocol*”) to be drafted by Affimed with contributions and input provided by Artiva according to Artiva’s responsibilities in the Combination Therapy Trial under this Agreement and the Development Plan, and approved by the JSC, subject to Section 3.5. Any amendments to a Protocol shall be subject to approval of the JSC (subject to Section 3.5) or by written agreement of the Parties.

**5.6 Informed Consent Form; Investigator’s Brochure.** Affimed shall prepare the patient informed consent form (“*ICF*”) for the Combination Therapy Trials conducted under the Development Plan (which shall include any required consent for the sharing and use of Combination Therapy Clinical Data under this Agreement) and provide a draft copy to Artiva for review, comment and any necessary input according to Artiva’s responsibilities in the Combination Therapy Trial under this Agreement and the Development Plan. Affimed shall consider and implement any comments from Artiva regarding the portion of the ICF relating to the use of Artiva Product. Any material changes to the ICF solely relating to the Artiva Product shall be subject to Artiva’s review and prior written consent. Any such proposed changes will be sent in writing to Artiva’s Alliance Manager. Artiva will provide such consent, or a written explanation for why such consent is being withheld, within [\*\*\*\*\*] Business Days of receiving a copy of Affimed’s requested changes; *provided* that if Artiva fails to provide such written explanation within such [\*\*\*\*\*]-Business Day period, then Artiva shall be deemed to have consented to such change or changes. Affimed shall provide the JSC with a copy of the final ICF for approval. Artiva shall provide to Affimed its investigator’s brochure (and regularly provide any updates) for the Artiva Product.

**5.7 Samples.** Samples collected in the course of Combination Therapy Trial activities shall be solely owned by Affimed (to the extent not owned by the patient and/or the clinical trial site), except that Samples collected in the course of the Confirmatory Combination Therapy Trial shall be jointly owned by the Parties in equal and undivided shares (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected and used solely in accordance with the applicable Protocol and ICFs. Except as set forth in the Development Plan, neither Party shall be permitted to use such Samples for any purpose without the approval of the JSC. All data and intellectual property arising out of such Samples use shall be considered Combination Therapy Clinical Data or Inventions, as applicable. Following completion of Development Plan Activities, Affimed shall have the first right to store the Samples for future use; *provided* that if Affimed determines that it no longer has a use for the Samples and Artiva determines that it does, then the Samples shall, subject to Applicable Laws and the terms of the signed ICFs, be transferred to Artiva and may be used solely thereafter by Artiva. If neither Party has any further use for the Samples, then the remaining Samples shall be destroyed pursuant to the respective Party’s standard operating procedures for sample destruction, subject to the terms of and permission(s) granted in the ICFs signed by the subjects contributing such Samples in the Combination Therapy Trials.

**5.8 Development Records.** Each Party shall maintain complete, current, and accurate records (in the form of technical notebooks or electronic files) of all Development activities

conducted by it under the Development Plan and all information resulting from such work (including, for clarity, all Combination Therapy Clinical Data). Each Party shall ensure that such records fully and properly reflect all Development activities performed and results achieved therefrom in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. To the extent required to meet a request by the FDA or any other Regulatory Authority, each Party shall permit the other Party upon reasonable advance written request to review and copy such records at reasonable times during normal business hours and to obtain access to originals of such records.

**5.9 Development Reports and Updates.** Each Party shall use Commercially Reasonable Efforts to provide the other Party with any deliverables described in the Development Plan in accordance with the timelines set out therein. At each regularly scheduled JSC meeting, each Party shall provide the JSC with regular reports detailing its Development activities for the Combination Therapy, the results of such activities, and if applicable, an update on its spend for the performance of any Confirmatory Combination Therapy Trial Activities. The Parties shall discuss the status, progress, and results of Development activities under this Agreement at such JSC meetings. Each Party shall respond in a timely fashion to any reasonable requests of the other Party for additional information related to such reports provided to the JSC. In addition to the foregoing reports and meetings with the JSC, each Party shall promptly provide the other Party with any material updates on Development of the Combination Therapy.

**5.10 Provision of Combination Therapy Clinical Data; Final Report.** In addition to its safety data and SAEs reporting obligations pursuant to Section 6.4 and the JSC reports as required in Section 5.9, Affirmed shall provide Artiva with [\*\*\*\*\*]. Affirmed shall provide Artiva the final version of the final report promptly following its completion.

**5.11 Materials Transfer.**

**(a) Materials.** To facilitate the Development of the Combination Therapy, either Party may provide to the other Party certain biological materials or chemical compounds (other than such Party's Product) Controlled by the supplying Party for use by the other Party (such materials or compounds, together with any progeny and derivatives thereof and improvements thereto, collectively, the "**Materials**"). All such Materials shall (i) remain the sole property of the supplying Party, (ii) be used only in the fulfillment of obligations or exercise of rights under this Agreement, subject to any limitations specified in writing by the supplying Party in connection with such provision, (iii) be used solely under the control of the recipient Party, (iv) not be used or delivered to or for the benefit of any Third Party (other than permitted subcontractors under Section 5.12) without the prior written consent of the supplying Party and (v) not be used in research or testing involving human subjects, unless expressly agreed in writing by the Parties.

**(b) Use Restrictions.** The recipient Party of the Materials shall (i) comply with all Applicable Laws regarding the handling and use of the Materials and (ii) not attempt to reverse engineer, deconstruct or in any way determine the structure or composition of the Materials. Any unused Materials shall be, at the supplying Party's discretion and instruction, either destroyed (with such destruction certified in writing) or returned to the supplying Party upon the expiration or any termination of this Agreement.

(c) **Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED UNDER THIS AGREEMENT, THE MATERIALS ARE PROVIDED “AS IS”. NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, OF ANY KIND, ARE GIVEN BY THE SUPPLYING PARTY WITH RESPECT TO ANY OF THE MATERIALS, INCLUDING THEIR CONDITION, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

#### 5.12 Subcontracting.

(a) **Permitted Subcontracting.** Subject to Section 5.12(b), each Party shall have the right to subcontract any portion of its obligations hereunder or under a Related Agreement to its own Affiliates or to Third Parties without the other Party’s prior written consent, including, for clarity, to contract research organizations or other Third Parties for activities in connection with the Combination Therapy Trial or CMC activities for such Party’s Product (e.g., manufacture, packing and testing), *provided* that before involving a Third Party for activities in connection with the Combination Therapy Trial for the first time, either Party shall provide to the JSC a high-level summary of the name and experience of that Third Party and reasonably take into consideration any concerns the other Party might raise through the JSC with respect to such Third Party. Exhibit 5.12(a) sets out a list of Third Parties that, as of the Effective Date, Affirmed and Artiva intend to engage as subcontractors for any material activities under this Agreement or the Development Plan.

(b) **Requirements.** Before allowing any Third Party subcontractor to begin performing any activity under this Agreement or a Related Agreement, the subcontracting Party shall enter into a written agreement with such subcontractor that obligates such subcontractor (and its personnel involved in the performance of such activity) to be bound by the terms and conditions of this Agreement (or the Related Agreement) applicable to the activity to be performed by such subcontractor in the same manner as such terms and conditions apply to such Party, including (i) the ownership and assignment of Inventions in accordance with Section 10.1 and (ii) the obligations of confidentiality and non-use no less stringent than those set forth in Article 11. The subcontracting Party shall be responsible for the direction and coordination of the performance of each subcontractor and shall ensure the subcontractor’s compliance with the terms and conditions of this Agreement. Each Party shall remain liable to the other Party for the acts and omissions of its subcontractors. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed directly against such subcontractor, for any obligation or performance hereunder, prior to proceeding directly against the subcontracting Party. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such subcontractors that are held by or under the control of such subcontractors and that are required to be provided to the other Party under this Agreement or the applicable Related Agreement.

5.13 **Quality Agreement.** Latest within [\*\*\*\*\*], the Parties shall enter into a clinical quality agreement (as may be amended in accordance with its terms, the “*Quality Agreement*”) which shall govern clinical quality issues relating to the conduct of Combination Therapy Trials, including quality issues relating to the Affirmed Product, the Artiva Product and the IL-2 Product.

#### 5.14 No Restrictions on Each Party's Product.

(a) **Provision of Products.** This Agreement does not create any obligation on the part of either Party to provide its Product for any activities other than the Development activities for the Combination Therapy as set forth in the Development Plan.

(b) **Clinical Trials; No Exclusive Relationship.** Subject to Section 4.3, as applicable, nothing in this Agreement shall (i) prohibit either Party from performing Clinical Trials relating to its own Product, either individually or in combination with any other compound or product, in any therapeutic area or (ii) create an exclusive relationship between the Parties with respect to any Product.

### 6. REGULATORY

#### 6.1 Overview.

(a) **Affirmed's Responsibility.** Affirmed shall be solely responsible for the following activities in connection with the Combination Therapy Trials:

(i) preparing, obtaining, and maintaining regulatory filings and approvals solely related to the Affirmed Product (including its use as part of the Combination Therapy in the Territory), *provided* that with respect to such regulatory filings and approvals, Affirmed shall use Commercially Reasonable Efforts to ensure that such regulatory filings and approvals are not in conflict with, or otherwise endanger, the Regulatory Materials or the use of the Affirmed Product as part of the Combination Therapy in the Territory;

(ii) acting as the sponsor of record as provided in 21 C.F.R. §312.50 or its equivalents, unless otherwise delegated in accordance with 21 C.F.R. §312.52 or its equivalents;

(iii) preparing and filing Regulatory Materials related to the Combination Therapy and Combination Therapy Trials during clinical development of the Combination Therapy, *provided* that Artiva shall have the right to review and comment on any Regulatory Materials related to the Combination Therapy as set forth in Section 6.2(a); and making all required submissions to Regulatory Authorities in the Territory related thereto on a timely basis;

(iv) listing each Combination Therapy Trial required to be listed on a public database, including clinicaltrials.gov or other public registry in any country in the Territory in which such Combination Therapy Trial is being conducted in accordance with Applicable Laws, and with Artiva's cooperation, in accordance with Affirmed's internal policies on clinical trial registration; and

(v) pursuant to Section 6.4 and the Pharmacovigilance Agreement, owning and being responsible for the maintenance of the global safety database and safety reporting for the Combination Therapy.

(b) **Artiva's Responsibility.** Artiva shall be solely responsible for preparing, obtaining, and maintaining all regulatory filings and approvals solely related to the Artiva Product (including its use as part of the Combination Therapy in the Territory), [\*\*\*\*\*].



## 6.2 Regulatory Matters.

(a) **Preparing and Filing Regulatory Materials during Clinical Development.** During the clinical development of the Combination Therapy in accordance with this Agreement and the Development Plan, Affimed shall be solely responsible for preparing and filing all Regulatory Materials for the Combination Therapy at its sole cost. During the clinical development, Affimed shall (i) be the holder of all Regulatory Materials for the Combination Therapy and (ii) have primary operational responsibility for interactions with the applicable Regulatory Authorities in the Territory with respect to the Combination Therapy. Upon Affimed's request, Artiva shall at its own cost provide reasonable support with respect to preparation of Regulatory Materials for the Combination Therapy, including by providing any data and information pertaining to the Artiva Product necessary for such filings (*provided* that Artiva may redact proprietary CMC, manufacturing process development information or any other information that Artiva reasonably determines to be competitively sensitive; provided further that if required by the applicable Regulatory Authority and upon Affimed's request, Artiva shall provide unredacted data and information directly to the Regulatory Authorities). Affimed shall provide Artiva with copies of proposed Regulatory Materials with respect to the Combination Therapy (except to the extent solely relating to the Affimed Product) reasonably prior to submission to the applicable Regulatory Authority, and Artiva shall have the right to review and comment on such Regulatory Materials. [\*\*\*\*\*]. Affimed shall promptly notify Artiva of all Regulatory Materials that Affimed submits for the Combination Therapy and shall promptly provide Artiva with a copy of such Regulatory Materials (except to the extent solely relating to the Affimed Product) submitted to the relevant Regulatory Authorities.

(b) **Interactions with Regulatory Authorities.** Affimed shall be responsible for engaging, interfacing, corresponding or meeting with any Regulatory Authority regarding Combination Therapy in the Territory. Affimed shall notify Artiva of any scheduled meeting or conference with any Regulatory Authority that relates to the Combination Therapy reasonably in advance of such meeting and shall provide Artiva with any material documentation prepared for such meeting or conference prior to such meeting or conference (except to the extent solely relating to the Affimed Product). In addition, Affimed shall promptly notify Artiva of any Regulatory Authority meetings or inspections, or any other events potentially impacting regulatory status of the Combination Therapy Trial or the Artiva Product promptly after Affimed becomes aware of such. Artiva shall have the right (but not the obligation) to have a reasonable number of its personnel attend and participate in any such meetings, conferences and inspections, to the extent permitted by Applicable Laws and to the extent they do not solely relate to the Affimed Product. Affimed shall (i) without undue delay provide Artiva with copies of all correspondence to or from, and minutes of material meetings (including, for clarity, telephone conferences) with, any Regulatory Authority relating to Development of the Combination Therapy, (ii) allow Artiva to review and provide comments on any correspondence to Regulatory Authority prior to submission, and (iii) consider Artiva's comments to such correspondence in good faith.

(c) **Preparing and Filing Regulatory Materials for Regulatory Approval and Commercialization.** Each Party shall use Commercially Reasonable Efforts to file for, obtain and maintain during the term of this Agreement, at its own cost, all Regulatory Approvals for its Product as required to Commercialize its Product as part of the Combination Therapy in the

Territory. To the extent required or useful, Affimed will coordinate the Parties' separate filings for Regulatory Approvals under this Section 6.2(c).

### **6.3 Right of Reference.**

(a) Each Party hereby grants to the other Party a "right of reference" (as defined in 21 C.F.R. §314.3(b)), or similar "right of reference" as defined in applicable regulations in the relevant jurisdiction, with respect to any regulatory filings and approvals Controlled by such Party or its Affiliates in the Territory that solely relates to its Product (including, for clarity, CMC information and the drug master file for its Product) and data contained therein solely to the extent necessary for the other Party to (i) obtain Regulatory Approval for, and conduct, the Combination Therapy Trials and (ii) perform its obligations and exercise its rights with respect to the Combination Therapy as expressly permitted under this Agreement, and for no other purpose.

(b) Affimed hereby grants to Artiva a "right of reference" (as defined in 21 C.F.R. §314.3(b)), or similar "right of reference" as defined in applicable regulations in the relevant jurisdiction, with respect to any Regulatory Materials for the Combination Therapy in the Territory and the Combination Therapy Clinical Data contained therein solely (i) to the extent necessary for Artiva to apply for, obtain and maintain Regulatory Approvals for the Artiva Product either as a monotherapy or in combination with, or as part of a combination therapy with, agents or products other than the Affimed Product (but in no case in combination with an Innate Cell Engager Technology other than the Affimed Product), and (ii) for inclusion in the safety database for the Artiva Product.

(c) Each Party shall provide to the other Party a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of reference set forth in Section 6.3(a) or Section 6.3(b). If, in any regulatory jurisdiction, it is not possible for a Party to provide such right of reference to the other Party pursuant to Section 6.3(a) or Section 6.3(b), such Party shall take commercially reasonable steps, subject to the terms and conditions of any applicable confidentiality obligations, to provide in lieu of such right of reference the right to use such regulatory filings, approvals and data contained therein (including, for clarity, Regulatory Materials and Combination Therapy Clinical Data contained therein) to the other Party solely for the purposes set forth in Section 6.3(a) or Section 6.3(b), as applicable. [\*\*\*\*\*]. Other than as set forth in this Section 6.3 and Section 4.2, no other right of reference (or right of use, as applicable) is granted by a Party to the other Party.

**6.4 Pharmacovigilance Agreement.** The Parties will execute a Pharmacovigilance Agreement latest within [\*\*\*\*\*] for the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations with respect to the use of the Products and the Combination Therapy and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement shall set forth the responsibilities of each Party with respect to safety data reporting, and shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of the Products and the Combination Therapy and shall ensure that adverse events associated with such Products and Combination Therapy and other safety information is exchanged according to a schedule that will permit each Party to comply with

Applicable Laws and regulatory requirements. Without limiting the generality of the foregoing, Affimed shall own, and shall be solely responsible for maintaining, the global safety database for the Combination Therapy, and shall be responsible for the safety reporting for the Combination Therapy to the applicable Regulatory Authority in the Territory. In the event of a conflict between the Pharmacovigilance Agreement and this Agreement, the Pharmacovigilance Agreement shall control with respect to its subject matter.

## 7. PROMOTION AND COMMERCIALIZATION

**7.1 Overview.** Subject to this Article 7 with respect to the Combination Therapy in the Territory, each Party shall have the right, at such Party's sole discretion and cost, to Commercialize such Party's Product worldwide, itself or with or through its Affiliates or any Third Parties. Affimed and its Affiliates shall have the sole right to Promote the Combination Therapy in the approved Indications in the Territory, provided that the foregoing shall not limit Artiva's right to reference the Promotional Materials for the Combination Therapy in connection with the Commercialization of the Artiva Product or participate in trade shows or conducting similar activities relating to the Combination Therapy, in each case in accordance with Applicable Law and provided that Artiva shall in each case only use Promotional Material for the Combination Therapy which has been approved by Affimed and, to the extent required, by the JCC pursuant to Section 3.3(b)(iii). For the avoidance of doubt, each Party shall be solely responsible for maintaining all Regulatory Approvals for the Combination Therapy in the Territory at its sole cost in accordance with Section 6.2(c).

### 7.2 Combination Therapy Promotion Plan.

**(a) Combination Therapy Promotion Plan.** Within [\*\*\*\*\*] days after Affimed's completion of a Pivotal/Registrational Trial of the Combination Therapy, or [\*\*\*\*\*] after Affimed's submission of its first application for Regulatory Approval for the Affimed Product for the Combination Therapy in the Territory, Affimed (or its Affiliate) shall submit to the JCC for review a written plan that sets forth a high-level Promotion strategy (which may include Affiliates of the Parties) with respect to the Combination Therapy (as may be amended, the "**Combination Therapy Promotion Plan**"). [\*\*\*\*\*].

**(b) Amendment to the Combination Therapy Promotion Plan.** The JCC shall regularly review and discuss the Combination Therapy Promotion Plan and subject to Section 3.5, the JCC may, as necessary, review and update the then-current Combination Therapy Promotion Plan. In the event of any inconsistency between the Combination Therapy Promotion Plan and this Agreement, the terms of this Agreement shall prevail.

### 7.3 Promotion of the Combination Therapy.

**(a) Launch Preparation of Products; Pricing.** Each Party shall be solely responsible for preparation of its Product for launch, including in relation to the Combination Therapy. As between the Parties, Affimed shall be solely responsible for determining the price of the Affimed Product, the ranges for any price increases or decreases, the annual price ranges for discounting or rebate, and price negotiations and other interactions with Third Party payors or purchasers of the Affimed Product in the Territory. As between the Parties, Artiva shall be solely

responsible for determining the price of the Artiva Product, the ranges for any price increases or decreases, the annual price ranges for discounting or rebate, and price negotiations and other interactions with Third Party payors or purchasers of the Artiva Product in the Territory.

**(b) Filling Orders; Booking of Sales.**

**(i)** As between the Parties, each Party shall be solely responsible for filling orders for its Product. Each Party shall book all sales of its Product by or on behalf of such Party, its Affiliates or licensees in accordance with the Accounting Standards. Each Party shall independently maintain an internal system, in accordance with the Accounting Standards and the In-Scope Adjusted Revenue Tracking Methodology, to separately track In-Scope Artiva Sales in the case of Artiva, and In-Scope Affirmed Sales in the case of Affirmed.

**(ii)** As between Affirmed and Artiva, Affirmed (or its Affiliate or licensee, as applicable) shall keep one hundred percent (100%) of proceeds generated from Affirmed's Commercialization of the Affirmed Product and Artiva (or its Affiliate or licensee, as applicable) shall keep one hundred percent (100%) of proceeds generated from Artiva's Commercialization of the Artiva Product, in each case subject to the payment obligation with respect to In-Scope Artiva Adjusted Revenue and In-Scope Affirmed Adjusted Revenue under Section 9.2.

**(c) Promotional Activities.**

**(i)** Affirmed (or its Affiliate), at its sole discretion, shall be responsible for promotional activities related to the launch and ongoing Commercialization of the Affirmed Product, including Promotional Materials for the Affirmed Product, that do not involve the Promotion of the Combination Therapy in the Territory. Artiva, at its sole discretion, shall be responsible for promotional activities related to the launch and ongoing Commercialization as specifically related to the Artiva Product, including Promotional Materials for the Artiva Product, that do not involve the Promotion of the Combination Therapy in the Territory.

**(ii)** Affirmed (or its Affiliate) shall be responsible for promotional activities related to the launch and ongoing Promotion of the Combination Therapy in accordance with Section 7.3(c). Subject to Section 7.3(c)(iv), Affirmed (or its Affiliate) shall be responsible for creating Promotional Materials for Promotion of the Combination Therapy for review and, if required according to Section 3.3(b)(iii), approval by the JCC. Prior to approval of the Promotional Materials for the Combination Therapy by the JCC, if required according to Section 3.3(b)(iii) (including the resolution of any dispute thereof in accordance with Section 3.5), Affirmed (or its Affiliate) shall Promote the applicable Combination Therapy in the Territory using only the approved product labels and inserts as related to the Combination Therapy approved by the applicable Regulatory Authority. Affirmed (or its Affiliate) shall be responsible for ensuring that such Promotional Materials for the Combination Therapy comply with Applicable Laws and the applicable Regulatory Approvals for the Combination Therapy. Either Party may submit updates to Promotional Materials for the Combination Therapy for review and, if required according to Section 3.3(b)(iii), approval by the JCC if (A) such update is based on relevant new scientific, medical or clinical data, relevant new regulatory or legal developments, or changes to the label or inserts approved by the applicable Regulatory Authority for the applicable Combination Therapy,

and (B) in the absence of such update, the use of the Promotional Materials would not comply with Applicable Laws in the Territory, and neither Party's representative(s) on the JCC shall unreasonably withhold approval, if required according to Section 3.3(b)(iii), to adopt such updates.

(iii) [\*\*\*\*\*].

(iv) Unless otherwise approved by the JCC, in the performance of Promotion of the Combination Therapy pursuant to this Agreement, neither Party shall use the trademarks, logos, Promotional Materials, trade dress, copyrights, corporate logos, corporate names, visual identity and branding elements of the other Party (or the other Party's other products) without the prior written consent of such other Party.

**7.4 Progress Updates for Promotion of Combination Therapy.** Through the JCC, Affimed shall provide Artiva with a summary of Affimed's Promotion of the Combination Therapy in the Field in the Territory since the last meeting of the JCC.

## 8. MANUFACTURE AND SUPPLY

### 8.1 Overview.

(a) **Clinical Demand Plan and Demand Projections.** As part of the Development Plan, the Parties shall agree on the initial projections of requirements of the Affimed Product, the Artiva Product and the IL-2 Product for the conduct of the Combination Therapy Trials ("**Clinical Demand Plan**"), to be updated from time to time, as required, through the JCC. [\*\*\*\*\*]. The Demand Projections shall be updated on a rolling quarterly basis through the JCC.

(b) **Affimed's Responsibility.** Affimed shall use Commercially Reasonable Efforts to supply (including all Manufacturing, acceptance and release testing) sufficient quantities of the Affimed Product in connection with the Development of the Combination Therapy as set forth in the Development Plan and Clinical Demand Plan and Commercialization of the Affimed Product for use in the Combination Therapy based on the Demand Projections, at Affimed's sole cost. Affimed shall ensure that the Affimed Product is Manufactured in accordance with Applicable Laws and the Quality Agreement and shall be of equivalent quality to the Affimed Product used by Affimed for its own development and commercialization of the Affimed Product in the Territory.

(c) **Artiva's Responsibility.** Artiva shall use Commercially Reasonable Efforts to supply (including all Manufacturing, acceptance and release testing) sufficient quantities of (i) the Artiva Product and IL-2 Product for the conduct of Combination Therapy Trials as set forth in the Development Plan and Clinical Demand Plan, and (ii) the Artiva Product in connection with Commercialization of the Artiva Product for use in the Combination Therapy based on the Demand Projections, in each case of clauses (i) and (ii), at Artiva's sole cost. Artiva shall ensure that the Artiva Product is Manufactured in accordance with Applicable Laws and the Quality Agreement and shall be of equivalent quality to the Artiva Product used by Artiva for its own development and commercialization of the Artiva Product in the Territory.

**8.2 Approvals.** Each Party is responsible for obtaining all approvals and permits (including facility licenses) that are required to Manufacture its Product in accordance with Applicable Law at its sole cost.

**8.3 Shortage; Allocation.** [\*\*\*\*\*].

**8.4 Manufacturing Records.** Each Party shall create and maintain complete and accurate records in all material respects pertaining to its Manufacture of its Product supplied hereunder in accordance with Applicable Laws.

**8.5 Quality.** Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Product, and for validation, documentation and release of its Product and such other quality assurance and quality control procedures in accordance with Applicable Laws.

## **9. FINANCIAL PROVISIONS**

**9.1 Development Costs.** If the Parties perform Confirmatory Combination Therapy Trial Activities in accordance with Section 5.4, within [\*\*\*\*\*] after the end of each Calendar Quarter, each Party shall provide to the other Party a written report of its actual FTE Costs and Out-of-Pocket Expenses incurred with respect to the performance of such Confirmatory Combination Therapy Trial Activities to be shared by the Parties in accordance with Section 5.4 for such Calendar Quarter. If requested by the other Party, the reporting Party will promptly provide invoices or other supporting documentation in sufficient detail to permit the other Party to confirm the accuracy of the reported actual FTE Costs and Out-of-Pocket Expenses pursuant to this Section 9.1. The Parties shall agree in writing on the calculation of any payment to be paid by Artiva to Affimed or by Affimed to Artiva so that each Party will bear fifty percent (50%) of the FTE Costs and Out-of-Pocket Expenses incurred by the Parties for the conduct of such Confirmatory Combination Therapy Trial Activities in accordance with Section 5.4. The Party that is owed a payment in accordance with the foregoing shall invoice the other Party for the amount of such payment and the other Party shall pay such invoiced amount within [\*\*\*\*\*] after delivery of such invoice; *provided* that, in the event of any dispute regarding any such payment owed by a Party under this Section 9.1, the undisputed portion of such payment shall be paid in accordance with the foregoing timeline by the applicable Party, and the remaining, disputed portion shall be paid after the Parties resolve such dispute in good faith.

### **9.2 Agreement Payments.**

**(a) Tracking Methodology.** Within [\*\*\*\*\*] after the latter of Affimed's and Artiva's submission of their respective first application for Regulatory Approval for the Combination Therapy in the Territory, the Parties shall mutually agree in writing on a methodology for tracking In-Scope Adjusted Revenue (the "**In-Scope Adjusted Revenue Tracking Methodology**"). [\*\*\*\*\*]. The JCC may, as necessary, review and update the In-Scope Adjusted Revenue Tracking Methodology; *provided* that, for avoidance of doubt, any changes will require mutual agreement by the Parties. If the Parties agree to use the same data source for the tracking of both Products, the Parties shall equally share those costs.

**(b) Reports.** Commencing upon the Calendar Quarter in which the First Commercial Sale of any In-Scope Artiva Sale occurs and thereafter during the Agreement Payments Term, Artiva shall, within [\*\*\*\*\*], unless extended by mutual agreement, after the end of such Calendar Quarter, provide Affimed with a report stating the In-Scope Artiva Adjusted Revenue during the applicable Calendar Quarter, calculated in accordance with Section 1.83 (expressed in local currency and converted to Dollars, if applicable). Commencing upon the Calendar Quarter in which First Commercial Sale of any In-Scope Affimed Sale occurs and thereafter during the Agreement Payments Term, Affimed shall, within [\*\*\*\*\*] days after the end of such Calendar Quarter, unless extended by mutual agreement, provide Artiva with a report stating the In-Scope Affimed Adjusted Revenue during the applicable Calendar Quarter calculated in accordance with Section 1.81 (expressed in local currency and converted to Dollars, if applicable). The format and content of each report shall be in the form outlined in the In-Scope Adjusted Revenue Tracking Methodology in accordance with Section 9.2(a).

**(c) Agreement Payments.** The Parties agree to Agreement Payments that achieve, after each Agreement Payment, an as adjusted proportion of Affimed In-Scope Adjusted Revenue to total In-Scope Adjusted Revenue (Affimed In-Scope Adjusted Revenue plus Artiva In-Scope Adjusted Revenue) equal to sixty-seven percent (67%) (the “**Agreed Value**”), unless otherwise adjusted pursuant to Section 16. Commencing upon the First Commercial Sale of any In-Scope Adjusted Revenue in the Field in the Territory and continuing during the Agreement Payments Term on a quarterly basis, Artiva shall pay to Affimed (or its designated Affiliate), or Affimed (or its designated Affiliate) shall pay to Artiva, a payment as follows (the “**Agreement Payments**”):

Agreement Payment = [ [ (In-Scope Affimed Adjusted Revenue ) + (In-Scope Artiva Adjusted Revenue ) ] x Agreed Value ] - In-Scope Affimed Adjusted Revenue

If the calculated Agreement Payment is a positive amount, Artiva shall pay the Agreement Payment for such Calendar Quarter to Affimed (or its designated Affiliate). If the calculated Agreement Payment is a negative amount, Affimed (or its designated Affiliate) shall pay the Agreement Payment for such Calendar Quarter to Artiva.

The Parties shall agree in writing on the Agreement Payment for a Calendar Quarter within [\*\*\*\*\*] days following the receipt of both the In-Scope Artiva Adjusted Revenue report and In-Scope Affimed Adjusted Revenue report for such Calendar Quarter, and the Party owing the Agreement Payment shall make such payment within [\*\*\*\*\*] after such agreement. [\*\*\*\*\*].

**9.3 Payments.** All payments by a Party to the other Party under this Agreement shall be made in US Dollars via electronic funds transfer in the requisite amount to such bank account as such other Party may from time to time designate by notice in writing to the paying Party, *provided* that any change in bank account shall become effective no earlier than the [\*\*\*\*\*] following the notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of any In-Scope Artiva Adjusted Revenue or In-Scope Affimed Adjusted Revenue) expressed in currencies other than Dollars), the Party responsible for such calculations shall convert any amount expressed in a foreign currency into US Dollar equivalents pursuant to Section 9.6. For clarity, any reference in this Agreement to \$ shall be construed as a reference to US Dollar.

## 9.4 Taxes.

(a) **Withholding Taxes.** Except as otherwise provided in this Section 9.4, each Party shall pay all income and other taxes (including interest) imposed on or measured with respect to its own income accruing with respect to payments pursuant to this Agreement. If Applicable Laws require the withholding of taxes from any payments made by either Party under this Agreement, such Party will make such withholding payments and will subtract the amount thereof from the payments made by it under this Agreement. The withholding Party will timely remit any amounts withheld under this provision to the appropriate governmental authority and will submit to the other Party appropriate proof of payment of the withheld taxes as well as the official receipts within a reasonable period of time. If the withholding Party determines that any withholding in respect of taxes is required with respect to any payment made by it to the other Party under this Agreement, such Party shall cooperate with and use best efforts to assist the other Party in order to allow the other Party to eliminate or mitigate any such withholding tax obligations with respect to such payments, including obtaining the benefit of any present or future treaty against double taxation which may apply to such payments. Without limiting the foregoing, the Parties each agree to inform the other as soon as reasonably practicable concerning any anticipated withholding taxes, cooperate in good faith to minimize the overall taxes, levies, imposts, duties and fees of whatever nature imposed in respect of the payments to be made under this Agreement; *provided* that the foregoing efforts shall not obligate either Party to expose itself or its Affiliates to any additional risk or increased external costs hereunder unless the other Party offers to reimburse such external costs. Prior to any payment to be made pursuant to this Agreement, each Party shall provide the other with such forms or documentation as may be reasonably necessary to eliminate or reduce any applicable withholding taxes, provided, that Affirmed shall satisfy this provision by providing Artiva with (i) an Internal Revenue Service Form W-8BEN-E, claiming eligibility for the benefits of the income tax treaty between the United States and Germany or (ii) causing its Affiliate that is entitled to receive payments pursuant to this Agreement with an Internal Revenue Service Form W-9, or such other Internal Revenue Service form establishing a reduction or elimination of withholding taxes on which Artiva can rely. It is further provided that Artiva shall satisfy this provision by providing Affirmed with an Internal Revenue Service Form W-9. Each Party represents that as of the date of this Agreement, based on present knowledge, it does not intend to withhold tax on payments to the other Party under this Agreement.

(b) **Later Imposed Withholding.**

(i) In the event that a Party (the "**Paying Party**") does not withhold taxes from a payment due to the other Party (the "**Recipient Party**") under this Agreement, and a governmental authority proposes to impose a liability in respect to withholding taxes in connection with such payment against the Paying Party (together with any penalties and interest imposed in connection therewith, a "**Later Imposed Withholding**") the Paying Party shall promptly notify the Recipient Party of such proposal, forward any information received and shall cooperate with the Recipient Party in evaluating any such claim. If the Recipient Party chooses to contest any such claim, it shall control any such contest at its own expense. The Paying Party shall reasonably cooperate with any such contest, including facilitating the Recipient Party's control thereof (e.g., by executing powers of attorney) and the Recipient Party shall reimburse the Paying Party for any reasonable out-of-pocket costs incurred in connection with such cooperation.



(ii) Upon either (i) a governmental authority successfully assessing a deficiency for any Later Imposed Withholding under a final determination in respect of such tax which, under applicable law, is not subject to further review, appeal or modification due to through proceedings or otherwise (including as a result of the expiration of a statute of limitations or period for the filing of claims for refunds, amended Tax Returns or appeals from adverse determinations), including a “determination” as defined in Section 1313(a) of the Code or analogous provisions of state, local or non-U.S. law, or (ii) the Recipient Party electing to not contest (or continue to contest) a proposed liability, the Recipient Party will indemnify the Paying Party for such Later Imposed Withholding.

(iii) At the Paying Party’s election, (i) the Paying Party may offset the amount of such Later Imposed Withholding indemnifiable pursuant to Section 9.4(b)(ii) from future payments due to the Recipient Party under this Agreement, or (ii) the Recipient Party shall pay the amount of such Later Imposed Withholding indemnifiable pursuant to Section 9.4(b)(ii) to the Paying Party promptly upon request. Promptly following the Paying Party withholding any Later Imposed Withholding or the Recipient Party remitting any Later Imposed Withholding to the Paying Party, the Paying Party will (A) pay to the relevant governmental authority the amount of such Later Imposed Withholding; and (B) provide evidence of such payment to the Recipient Party on a reasonable and timely basis. In the event that any Later Imposed Withholding is subsequently reduced, the Parties shall ensure that the benefit of such reduction is paid over to the Recipient Party.

(c) VAT. All payments or other consideration payable under this Agreement are exclusive of VAT. If and to the extent VAT (i) is properly chargeable in accordance with applicable laws in respect of, or as a result of, any supplies of goods or services, or sales rendered under this Agreement and (ii) is to be paid to the competent tax authorities by the Party making such supply of goods or services, or sales, the receiving Party shall pay, in addition to the payment (or the provision of other consideration for such supply or sales), an amount equal to such VAT at the applicable rate to the providing Party upon receipt of a valid VAT invoice (or, if later, on the due date for payment (or the provision of such other consideration) for such supply or sale). The Parties shall issue invoices for all amounts payable or other consideration provided under this Agreement consistent with applicable VAT laws and regulations and irrespective of whether the sums or other consideration may be netted for settlement purposes. Each Party shall provide such information as is reasonably requested by the other Party to enable the recovery, as permitted by applicable laws, of any VAT charged in respect of any supplies of goods or services, or sales, rendered under this Agreement, such recovery being for the benefit of the Party bearing the economic cost of such VAT under this Section 9.4(c). Notwithstanding the foregoing, if as a result of any assignment or sublicense by the Party providing the supply or service, any change in such providing Party’s tax residency, any change in the entity that provides the supply or service, or any failure on the part of such providing Party to comply with applicable law (other than any failure resulting from reliance on any certification or other information provided by the Party receiving the supply or service with respect to the amount of applicable VAT) with respect to VAT (including filing or record retention requirements), VAT is imposed that would not otherwise have been imposed (“**Incremental VAT**”), then, if and to the extent such Incremental VAT cannot be offset or recovered by means of an input VAT deduction by the Party receiving the supply or service, the Party providing the supply or service shall be solely responsible for the amount of such Incremental VAT and shall indemnify the Party receiving the supply or service so that such

receiving Party is left in the same after-Tax position it would have been in had there been no such imposition of Incremental VAT.

(d) Where under the terms of this Agreement, one Party is liable to indemnify or reimburse another person in respect of any costs, charges or expenses, the payment shall only include an amount equal to any VAT thereon not recoverable by the other Party (or the principal or representative member of any VAT group of which it forms part), subject to that Party (or representative member) taking all reasonable steps to recover such amount of VAT as may be practicable.

(e) **Foreign Derived Intangible Income.** Affirmed shall use Commercially Reasonable Efforts to provide, and to cause its Affiliates, subcontractors, sublicenses, customers, and applicable Third Parties to provide, any information and documentation reasonably requested by Artiva and reasonably available to Affirmed to obtain the benefits of Section 250 of the Internal Revenue Code of 1986, as amended and the applicable Treasury Regulations, with Artiva reimbursing Affirmed for all out-of-pocket costs.

**9.5 Interest.** If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon. All interest shall accrue and be calculated on a daily basis (both before and after any judgment) at a rate per annum equal to [\*\*\*\*\*] above the then current “prime rate” in effect published in *The Wall Street Journal (U.S., Eastern Edition)*, but in no event in excess of the maximum rate permissible under applicable law, for the period from the due date for payment until the date of actual payment.

**9.6 Currency; Exchange Rate.** All payments under this Agreement shall be payable in US Dollars. When conversion of payments from any foreign currency is required in connection with the payment of any payment obligations under this Agreement, such conversion shall be made by each Party according to the conversion mechanism it generally applies under its Accounting Standards.

**9.7 Financial Records; Audit.**

(a) **Record-Keeping Obligations.** Each Party shall, and shall cause its Affiliates and (using reasonable efforts) its licensees to, keep and maintain complete and accurate books and records pertaining to: (i) all costs incurred by such Party in connection with the performance of Confirmatory Combination Therapy Trial Activities in sufficient detail to permit the other Party to confirm the basis and accuracy of the costs incurred by such Party under this Agreement; (ii) inputs necessary to calculate the Agreement Payment in accordance with Section 9.2(c); (iii) with respect to Artiva only, all In-Scope Artiva Adjusted Revenue, and (iv) with respect to Affirmed only, all In-Scope Affirmed Adjusted Revenue. Such books and records shall be retained by such Party (and its Affiliates and licensees) until the later of: (A) [\*\*\*\*\*] after the end of the period to which such books and records pertain; or (B) the expiration of the applicable tax statute of limitations (including any extensions thereof), or for such longer period as may be required by Applicable Law.

(b) **Audit.** At the request of the other Party, each Party shall, and shall cause its Affiliates and (using reasonable efforts) its (sub-)licensees to, permit an independent public

accounting firm of internationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 9.7(a) to ensure the accuracy of all reports, invoices and payments made hereunder. [\*\*\*\*\*]. The accounting firm shall disclose to the auditing Party only whether the audited information is correct or incorrect and the specific details concerning any discrepancies. Except as provided below, the cost of any audit conducted pursuant to this Section 9.7(b) shall be borne by the auditing Party, unless the audit reveals a variance of more than [\*\*\*\*\*] from the reported or invoiced amounts, in which case, the audited Party shall bear the full cost of the audit. If such audit concludes that (A) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, plus interest calculated in accordance with Section 9.5 or (B) excess payments were made by the audited Party, the auditing Party shall reimburse the audited Party for any such excess payments, in each case of clause (A) or (B), within [\*\*\*\*\*] of the accounting firm's audit report.

## 10. INTELLECTUAL PROPERTY

### 10.1 Ownership.

(a) **Background Technology.** Subject to the rights granted under Section 4.1, (i) Artiva will retain all rights, title, and interests in and to Artiva Background Technology, (ii) Affimed will retain all rights, title, and interests in and to Affimed Background Technology, and (iii) each Party will retain its joint rights, title and interest in and to all Joint Background Patents and Joint Background Know-How.

#### (b) Program Inventions

(i) **Artiva Product Inventions.** Artiva shall solely own all rights, title, and interest in and to any and all Inventions (and intellectual property rights therein) that solely constitute an improvement or enhancement to Artiva Background Technology, including any Inventions (and intellectual property rights therein) solely relating to [\*\*\*\*\*] ("**Artiva Product Inventions**"). Affimed hereby irrevocably assigns to Artiva all its rights, title and interest in and to all Artiva Product Inventions. Artiva Product Inventions shall be the Confidential Information of Artiva.

(ii) **Affimed Inventions.** Affimed shall solely own all rights, title, and interest in and to any and all Inventions (and intellectual property rights therein) that solely constitutes an improvement or enhancement to any Affimed Background Technology, including any Inventions (and intellectual property rights therein) solely relating to [\*\*\*\*\*] ("**Affimed Inventions**"). Artiva hereby irrevocably assigns to Affimed all its rights, title and interest in and to all Affimed Inventions. Affimed Inventions shall be the Confidential Information of Affimed.

(iii) **Joint Collaboration Inventions.** The Parties shall jointly own all rights, title, and interest in and to any and all Inventions that are not Affimed Inventions or Artiva Product Inventions, including all intellectual property rights therein ("**Joint Collaboration Inventions**"), and all Patents claiming any Joint Collaboration Invention ("**Joint Collaboration Patents**"). Each Party hereby assigns to the other Party such interest in such Joint Collaboration Inventions and Joint Collaboration Patents as necessary to vest joint ownership in the Parties.

Except as expressly provided under this Agreement, unless otherwise agreed by the Parties on a commercially reasonable royalty or other compensation for the practice of such Joint Collaboration Inventions or any Joint Collaboration Patents, neither Party shall have any rights to license, assign or exploit its interests in any Joint Collaboration Invention or Joint Collaboration Patent anywhere in the world. [\*\*\*\*\*].

(c) **Non-Program Inventions.** The Parties acknowledge and agree that each of the Parties Controls and may gain Control over certain Know-How and other intellectual property rights with respect to NK Cell technology and/or Innate Cell Engager Technology through activities outside the scope of the collaboration hereunder and independent of the Parties' performance hereunder or the Combination Therapy Trials or activities under the Development Plan, which are in each case not provided by the Controlling Party nor used for the conduct of the Combination Therapy Trial or activities under the Development Plan (the "**Non-Program Inventions**"). The Party that Controls such Non-Program Inventions shall retain all rights, title, and interests in and to such Non-Program Inventions, and such Non-Program Inventions shall not be subject to Section 10.1(b).

## 10.2 Prosecution and Maintenance.

(a) **Product Patents.** Artiva shall have the sole right, at its sole expense, to Prosecute and Maintain, defend and enforce any and all Patents that Cover an Artiva Product Invention (and not an Affirmed Invention or Joint Collaboration Invention) ("**Artiva Product Patents**"). Affirmed shall have the sole right, at its sole expense, to Prosecute and Maintain, defend and enforce any and all Patents that Cover an Affirmed Invention (and not an Artiva Product Invention or Joint Collaboration Invention) ("**Affirmed Patents**"). [\*\*\*\*\*].

### (b) Joint Patents.

(i) Promptly following the Effective Date, patent representatives of each of the Parties shall discuss the patenting strategy for any Joint Collaboration Inventions which may arise. In particular, the Parties shall discuss whether to file a Joint Patent and the strategy for the Prosecution and Maintenance of such Joint Patent. For the avoidance of doubt, (i) any Patent that Covers both (A) an Artiva Product Invention and (B) any other Invention, and (ii) any Patent that Covers both (1) an Affirmed Invention and (2) any other Invention, in each case of ((i) and (ii)), shall be a Joint Patent. [\*\*\*\*\*].

(ii) [\*\*\*\*\*].

## 10.3 Enforcement.

(a) **Notice.** Each Party shall notify the other Party in writing of any threatened or actual infringement, misuse, or misappropriation by any Third Party of any Joint Technology (including any Joint Patent), or any declaratory judgment action relating thereto ("**Infringement**"), promptly after becoming aware of any such Infringement.

(b) **Coordination; Recovery.** The Parties will promptly meet, discuss and agree, in light of the circumstances of such Infringement, which Party should take the lead or whether the Parties should jointly lead in initiating legal action to enforce any Joint Patents against

infringement, and to protect any Know-How within Joint Technology from misappropriation, or to defend any declaratory judgment action relating thereto. If the Parties mutually agree to initiate such legal proceeding, each Party shall be responsible for [\*\*\*\*\*] of the reasonable, verifiable, and out-of-pocket costs incurred in connection with such action. [\*\*\*\*\*].

(c) **Allocation of Recoveries.** Any damages recovered from a Third Party in an Infringement action shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated *pro rata* if insufficient to cover the totality of such expenses), [\*\*\*\*\*].

#### 10.4 Infringement of Third Party Rights.

(a) **Notice.** If the Development or Promotion of the Combination Therapy or the conduct of any Combination Therapy Trial becomes the subject of a claim of infringement of a Patent, copyright, or other proprietary right by a Third Party, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim and the appropriate course of action and may, if appropriate, agree on and enter into a “common interest agreement” wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute.

(b) **Coordination; Recovery.** If an infringement claim described in Section 10.4(a) is brought against one or both Parties, except as provided in the last sentence of this Section 10.4(b), the Parties shall defend such claim jointly, unless they agree otherwise in writing. [\*\*\*\*\*]. If the charged Party does not commence actions to defend such claim within thirty (30) days after being so charged, then the other Party shall have the right, but not the obligation, to defend such claim. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider in good faith the non-defending Party’s comments and suggestions on strategy for defending such action. The Party defending the claim shall bear the costs of the defense of any such claim and shall have sole rights to any recovery. No Party shall enter into any settlement concerning activities under this Agreement or any Combination Therapy that affects the other Party’s rights under this Agreement or imposes any obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party’s prior written consent, such consent not to be unreasonably withheld or delayed. Notwithstanding the foregoing, if a claim of infringement described in Section 10.4(a) is attributable solely to one Party’s Development, Manufacture or Commercialization of its Product, such Party shall have the sole right and obligation, to defend and settle the disposition of such claim, at its sole expense, in a manner not to materially adversely impact the other Party’s rights under this Agreement.

10.5 **Use of Confidential Information.** Except as expressly provided in Section 10.2, each Party agrees to make no patent application based on the other Party’s sole Confidential Information, to incorporate any Confidential Information solely owned by the other Party into a patent application, and to give no assistance to any Third Party for such application, without the other Party’s prior written authorization.

**10.6 Inventor Compensation.** Each Party shall be responsible for payment of any consideration which it is required to pay to its employees or independent consultants or subcontractors as compensation for the assignment of rights to any Artiva Product Inventions, Affirmed Inventions, or Joint Collaboration Inventions, as applicable, according to the legal provisions applicable in the relevant country and/or a contractual obligation.

**10.7 Joint Research Agreement.** The Parties acknowledge and agree that this Agreement will be deemed to be a joint research agreement as referenced in 35 United States Code Section 102(c), and that Inventions arising under this Agreement are intended to have the benefit of the rights and protections conferred hereunder.

## 11. CONFIDENTIALITY

**11.1 Definition and Ownership of Confidential Information.** As used herein, “*Confidential Information*” of a Party means any and all nonpublic information (including Know-How) of such Party that is disclosed in connection with this Agreement or any Related Agreement (whether orally, electronically, visually or in writing) by or on behalf of such Party to the other Party or its designee. Except as otherwise expressly provided in the Agreement, Inventions and other intellectual property shall be the Confidential Information of the Party(ies) that own such Inventions and other intellectual property. [\*\*\*\*\*]. The terms and conditions of this Agreement shall be Confidential Information of both Parties.

### 11.2 Disclosure and Use of Confidential Information.

(a) **Confidentiality and Non-Use Obligations.** Except to the extent expressly authorized by this Agreement, each Party (for purposes of this Article 11, the “*Receiving Party*”) in possession of Confidential Information of the other Party (for purposes of this Article 11, the “*Disclosing Party*”) shall: (i) hold in confidence and not disclose the Disclosing Party’s Confidential Information to any Third Party without prior written consent of the Disclosing Party, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, and (ii) only use (or permit the use of) the Disclosing Party’s Confidential Information as expressly permitted by this Agreement or any Related Agreement or for the performance of the Receiving Party’s obligations or the exercise of the Receiving Party’s rights under this Agreement or any Related Agreement; provided that, notwithstanding the foregoing ((i) and (ii)), with respect to any Confidential Information that constitutes Combination Therapy Clinical Data, the applicable Receiving Party shall have the right to use such Combination Therapy Clinical Data as provided in Section 4.2.

(b) **Exceptions.** The Receiving Party’s obligations set forth in Section 11.2(a) shall not apply to that portion of the Disclosing Party’s Confidential Information to the extent that the Receiving Party establishes by contemporaneous written evidence that such Confidential Information:

(i) was known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(ii) was generally available to the public or otherwise part of the public domain, at the time of disclosure by the Disclosing Party;

(iii) becomes generally available to the public or otherwise part of the public domain after the disclosure by the Disclosing Party, other than through any act or omission of the Receiving Party in breach of this Agreement;

(iv) is subsequently disclosed to the Receiving Party by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the Disclosing Party; or

(v) is subsequently and independently developed by employees, subcontractors or sublicensees of the Receiving Party or its Affiliates without use of or reference to the Disclosing Party's Confidential Information, other than through any act or omission of the Receiving Party in breach of this Agreement.

### 11.3 Authorized Disclosures.

(a) **Applicable Law.** The Receiving Party may disclose the Disclosing Party's Confidential Information if such disclosure is required by Applicable Law (including to comply with the order of a court of competent jurisdiction or in connection with any filing with a securities exchange), but only to the extent such disclosure is reasonably necessary for such compliance; *provided, however,* except as otherwise required or necessitated by such Applicable Law, the Receiving Party shall provide prompt written notice of such disclosure requirement to the Disclosing Party and provide reasonable assistance to enable the Disclosing Party to seek a protective order or otherwise limit or prevent such disclosure. In any event, the Receiving Party shall only disclose that portion of the Confidential Information that is legally required to be disclosed. Any Confidential Information that is disclosed in order to comply with Applicable Law pursuant to this Section 11.3(a) will remain otherwise subject to the confidentiality and non-use provisions of this Article 11 with respect to such Receiving Party disclosing such Confidential Information.

(b) **Regulatory Authorities.** The Receiving Party may disclose the Disclosing Party's Confidential Information to Regulatory Authorities to the extent such disclosure is required to comply with Applicable Laws or is in connection with such Party's regulatory filings, submissions and communications with Regulatory Authorities regarding such Party's Product.

(c) **Combination Therapy Trials.** The Receiving Party may disclose the Disclosing Party's Confidential Information to Third Party subcontractors engaged by the Receiving Party in accordance with Section 5.12(b) to the extent such disclosure is required to conduct the Combination Therapy Trials or to otherwise fulfill its obligations under this Agreement; *provided, however,* that any such subcontractors must be contractually bound in writing by obligations substantially similar to those set forth in this Article 11 and comply with other requirements set forth in Section 5.12(b).

(d) **Prosecution and Maintenance of Patents.** The Receiving Party may disclose the Disclosing Party's Confidential Information to the extent such disclosure is required for the Receiving Party's Prosecution and Maintenance of Affirmed Patents or Joint Patents (in the case the Receiving Party is Affirmed), or Artiva Product Patents (in the case the Receiving Party is Artiva), in each case, as contemplated by this Agreement and in accordance with Section 10.2.

(e) **Other Authorized Disclosures.** The Receiving Party may disclose the Disclosing Party's Confidential Information, on a confidential basis and to the extent reasonably necessary, to its Affiliates, employees, board members, accountants, attorneys, auditors and other professional, scientific and medical advisors for the sole purpose of enabling such disclosees to provide advice to such Party in connection with the research, development or commercialization of such Party's Product (and except to the extent such disclosee is or could reasonably be expected to be in a conflict of interest in respect of such Confidential Information, or such disclosure would be against applicable insider trading rules). [\*\*\*\*\*].

(f) **Terms of this Agreement.** The Parties acknowledge that either or both Parties may be obligated to file under Applicable Laws a copy of this Agreement with the SEC or other similar governmental authorities. Each Party shall be entitled to make such a required filing, *provided* that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party and permitted by such governmental authority. In the event of any such filing, the filing Party will consult with the other Party on the provisions of this Agreement to be redacted in any filing made with the SEC or as otherwise required by Applicable Laws; *provided* that the filing Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws.

**11.4 Continuing Obligation.** Article 11 shall survive the expiration or termination of this Agreement for a period of [\*\*\*\*\*].

**11.5 Personal Information.** All Confidential Information containing Personal Information shall be handled in accordance with all Applicable Laws relating to data protection and privacy.

**11.6 Return or Destruction of Confidential Information.** Upon expiration or any early termination of this Agreement, or upon the Disclosing Party's earlier written request, the Receiving Party shall either return to the Disclosing Party or destroy (at the Disclosing Party's option): (a) all Confidential Information (including all copies, records and other embodiments thereof, in any medium) in its possession (with the exception of one (1) copy of such Confidential Information, which may be retained by the legal department of the Receiving Party in its secure archives to confirm compliance with the non-use and non-disclosure obligations under this Agreement); and (b) any Confidential Information of the Disclosing Party contained in its laboratory notebooks or databases; *provided* that (with respect to both clauses (a) and (b)) the Receiving Party may retain and continue to use such solely-owned Confidential Information of the other Party, to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement; *provided, further*, that (with respect to both clauses (a) and (b)) such Confidential Information of the Disclosing Party existing on any backup, back-end, or archiving system, or in electronic files of the Receiving Party that are not reasonably accessible, and which cannot be reasonably deleted from such systems or files, may be retained by the Receiving Party.

## **12. PRESS RELEASES AND PUBLICATIONS**

**12.1 Press Release; Public Disclosure.** The Parties shall jointly agree to the content and timing of all external communications with respect to this Agreement, including an initial



press release to be jointly issued by the Parties in the form attached hereto as Exhibit 12.1, subsequent press releases, media Q&As, and the content and wording of any listing of a Combination Therapy Trial on a public database or public registry (such as clinicaltrials.gov).

Both Parties may make subsequent press release or public disclosure of prior disclosures agreed by the Parties; *provided* that such subsequent disclosure does not (a) include any new data or information, conclusions, or other non-public information about the other Party, or (b) present the previously agreed content in a form or manner that materially alters the conclusion or subject matter therein.

## **12.2 Publication of Combination Therapy Clinical Data.**

**(a) Registration; Initial Publication of Combination Therapy Clinical Data.** To the extent required by Applicable Law, Affimed will register the Combination Therapy Trials with the clinical trials registry located at clinicaltrials.gov. Any publication of the Combination Therapy Clinical Data will be in accordance with the terms of this Agreement and the Protocol. The initial publication of the Combination Therapy Clinical Data will be a joint publication of both Parties, in a substance and form to be agreed by and through the JSC and in accordance with the strategy approved by the JEC; *provided* that the JSC representatives may not unreasonably withhold, condition or delay their consent to such substance or form.

**(b) Publication.** Subject to Section 12.2(a), each Party shall use Commercially Reasonable Efforts to publish scientific paper, letter or any other manuscript in a scientific journal or present any abstract, poster, talk or any other presentation, in either case related to the Combination Therapy Clinical Data (each, a “**Publication**”) in accordance with accepted scientific practice and the procedures set forth in this Section 12.2(b). The Party proposing to publish or present a Publication shall deliver to the other Party a copy of the proposed Publication: (i) for abstracts, posters or slide presentations, at least [\*\*\*\*\*] prior to submission (in the case of abstracts) or first public presentation (in the case of posters and slide presentations); and (ii) at least [\*\*\*\*\*] in advance of first submission and each subsequent submission in the case of scientific papers, letters or any other manuscripts; or (iii) within such other timeframe as the Parties may agree. The reviewing Party shall determine whether any of its Confidential Information [\*\*\*\*\*] that may be disclosed in such Publication should be modified or deleted, whether to file a Patent application on any Affimed Invention (solely with respect to Affimed) or Artiva Product Invention (solely with respect to Artiva) or Joint Collaboration Invention disclosed therein. The presentation or submission of such Publication shall be delayed for an additional [\*\*\*\*\*] if a reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant Patent applications. If a reviewing Party reasonably requests modifications to the Publication to prevent the disclosure of such Party’s Confidential Information, the publishing Party shall remove such information prior to the presentation or submission of such Publication. The Parties shall work in good faith and in a timely manner to resolve any disagreement as to the content, timing, and/or venue or forum for such Publication. Authorship of any Publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed publication or presentation.

**12.3 Acknowledgements.** Each Party agrees to identify and acknowledge the other Party’s support in any press release and any Publication.

**13. REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMERS.**

**13.1 Mutual Representations and Warranties.** Each Party represents and warrants to the other Party that as of the Effective Date:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

(b) it has the full right and authority to enter into this Agreement and to perform all of its obligations hereunder;

(c) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(d) it has taken all other action necessary to authorize such execution, delivery and performance as required by Applicable Law, its certificate of incorporation, by-laws or other organizational documents or any agreement to which it is a party or to which it may be subject;

(e) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(f) it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement;

(g) neither the execution and delivery of this Agreement nor the performance hereof by it requires it to obtain any permits, authorizations or consents from any governmental authority (other than any Regulatory Approvals) or from any other person, firm or corporation, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination, rescission, renegotiation or acceleration under, or trigger any other rights under, any agreement or contract to which it is a party or to which it may be subject that relates to Affimed Background Technology in the case of Affimed, or to Artiva Background Technology in the case of Artiva;

(h) [\*\*\*\*\*];

(i) [\*\*\*\*\*]; and

(j) to the best of its knowledge:

(i) [\*\*\*\*\*]; and

(ii) [\*\*\*\*\*].

### 13.2 Covenants.

(a) **Compliance.** Each Party hereby covenants to the other Party that it shall carry out (i) the Development and Promotion of the Combination Therapy, (ii) Commercialization of its Product and (iii) its other obligations or activities hereunder in accordance with: (A) the terms of this Agreement, the Development Plan, the Combination Therapy Promotion Plan and the Related Agreements and (B) all Applicable Laws and Regulatory Approvals. Without limiting the foregoing, each Party shall (x) maintain appropriate policies, practices and procedures to ensure its compliance with all applicable Healthcare Laws, and (y) track and report to applicable Regulatory Authorities information relating to pricing and/or transfers of value to healthcare providers, teaching hospitals and other Third Parties with respect to its activities and/or operations regarding the applicable Product Commercialized by or on behalf of such Party.

(b) **No Debarment.** Neither Party nor any of its Affiliates shall use in any capacity, in connection with the performance of its obligations under this Agreement, any person or entity that has been Debarred. Each Party agrees to inform the other Party in writing promptly if it learns that it or any person or entity that is performing activities in connection with this Agreement is Debarred or is subject to Debarment or, to the notifying Party's knowledge, if Debarment of the notifying Party or any person or entity used in any capacity by such Party or any of its Affiliates in connection with the performance of its other obligations under this Agreement, is threatened.

(c) **FCPA.** Each Party hereby covenants to the other Party, on behalf of itself and its officers, directors, employees, Affiliates and agents, that, in connection with the matters that are the subject of this Agreement, and the performance of its obligations hereunder, it shall (i) comply with the U.S. Foreign Corrupt Practices Act (to extent applicable), as amended, and any other Applicable Law relating to or concerning public or commercial bribery or corruption and its applicable anti-corruption policies and (ii) not take any action that will cause the other Party or its Affiliates to be in violation of any such laws or policies.

(d) **No Conflicts.** During the Term, neither Party shall, or shall allow its Affiliates to, enter into any agreement granting a license or other right that is inconsistent with the rights granted to the other Party under this Agreement.

### 13.3 Disclaimers.

(a) **Combination Therapy Trials.** Neither Party makes any assurances that the Combination Therapy Trials will lead to any particular result. Each Party acknowledges that the success of the Combination Therapy Trials is not guaranteed. Neither Party accepts any liability for any use that the other Party may make of the Combination Therapy Clinical Data nor for advice or information given in connection therewith.

(b) **General.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON

**14. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE.**

**14.1 Indemnification by Affirmed.** Affirmed shall defend, indemnify and hold harmless Artiva, its Affiliates, and its and their employees, directors, subcontractors and agents (collectively, the “*Artiva Indemnitees*”) from and against any liabilities, damages, settlements, penalties, fines, reasonable costs and expenses (including, reasonable attorneys’ fees and other expenses of litigation) (collectively, “*Losses*”) resulting from Third Party suits, claims, actions, allegations and demands (each, a “*Third Party Claim*”) against an Artiva Indemnatee to the extent that they arise or result from: (a) the negligence or willful misconduct by any Affirmed Indemnatee in connection with this Agreement, (b) a breach by Affirmed of any of its representations, warranties, covenants or other obligations of Affirmed under this Agreement, (c) any Later Imposed Withholding (subject to Section 9.4(b)), (d) any injury to a subject in the Combination Therapy Trial to the extent attributable to the Affirmed Product, (e) any injury to a customer or end-user of Combination Therapy to the extent attributable to the Affirmed Product or (f) the use by Affirmed, its Affiliates, contractors or licensees of Combination Therapy Clinical Data, Affirmed Inventions, or Joint Technology (including Joint Patents); but excluding, in each case (of (a) through (f)), any such Losses to the extent arising or resulting from a cause or event for which Artiva is obligated to indemnify the Affirmed Indemnitees pursuant to Section 14.2.

**14.2 Indemnification by Artiva.** Artiva shall defend, indemnify and hold harmless Affirmed, its Affiliates, and its and their employees, directors, subcontractors and agents (collectively, the “*Affirmed Indemnitees*”) from and against any Losses resulting from Third Party Claims against an Affirmed Indemnatee to the extent that they arise or result from: (a) the negligence or willful misconduct by any Artiva Indemnatee in connection with this Agreement, (b) a breach by Artiva of any of its representations, warranties, covenants or other obligations of Artiva under this Agreement, (c) any Later Imposed Withholding (subject to Section 9.4(b)) (d) any injury to a subject in the Combination Therapy Trial to the extent attributable to the Artiva Product, (e) any injury to a customer or end-user of Combination Therapy to the extent attributable to the Artiva Product or (f) the use by Artiva, its Affiliates, contractors or licensees of Combination Therapy Clinical Data, Artiva Product Inventions, or Joint Technology (including Joint Patents); but excluding, in each case (of (a) through (f)), any such Losses to the extent arising or resulting from a cause or event for which Affirmed is obligated to indemnify the Artiva Indemnitees pursuant to Section 14.1.

**14.3 Procedure.** Each Party’s indemnification obligations under Section 14.1 and Section 14.2 are conditioned upon the Party seeking indemnification (the “*Indemnatee*”) delivering a written notice to the other Party (the “*Indemnitor*”) of any applicable Third Party Claim subject to indemnification hereunder promptly after the Indemnatee becomes aware of such Third Party Claim. The Indemnitor will have no indemnification obligations hereunder to the extent materially prejudiced by any delay by the Indemnatee in providing such notice. The Indemnitor will have the sole right to defend or settle (subject to the remainder of this Section 14.3) any Third Party Claim (using counsel reasonably satisfactory to the Indemnatee). The Indemnatee will cooperate fully with Indemnitor in connection therewith, at the Indemnitor’s expense. The

Indemnitee may participate in (but not control) the defense thereof at its sole cost and expense. The Indemnitor shall keep the Indemnitee advised of the status of the Third Party Claim and the defense thereof and shall reasonably consider recommendations made by the Indemnitee with respect thereto. The Indemnitee shall not agree to any settlement of any Third Party Claim without the prior written consent of the Indemnitee, which shall not be unreasonably withheld, delayed or conditioned. The Indemnitor shall not agree to any settlement of any Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnitee from all liability with respect thereto or that imposes any liability or obligation on the Indemnitee without the prior written consent of the Indemnitee, which shall not be unreasonably withheld, delayed or conditioned.

**14.4 Limitation of Liability.** EXCEPT WITH RESPECT TO (a) CLAIMS INDEMNIFIABLE UNDER SECTION 14.1 AND SECTION 14.2, (b) BREACH OF ARTICLE 11 OR (c) INSTANCES OF FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, INCLUDING LOSS OF PROFITS OR ANTICIPATED SALES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

**14.5 Insurance.** As long as any Combination Therapy is being clinically tested in human subjects, each Party shall place and maintain public and general liability insurance with a limit of [\*\*\*\*\*]. There will be separate insurance coverage for Clinical Trials on a so-called non-fault basis. Such policy will be placed for the entire duration of any Combination Therapy Trial until its termination. Thereafter there will be an extended reporting period of at least five (5) years, which will allow the study subject to make a claim directly with the respective insurer. The study subject only has to prove a causal relationship between the study and the bodily suffering rather than any kind of negligence of any of the involved parties. Upon start of Commercialization, the Parties agree to extend the liability coverage and place products liability insurance with an appropriate limit or what is legally required. Such insurance does not create a limit of either Party's liability with respect to its indemnification obligations under this Article 14. Each Party shall provide the other Party with a certificate of insurance evidencing such Party's compliance with this Section 14.5 upon request. Each Party's liability policy shall include the other Party as an additional insured. Each Party shall provide the other with a prior written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance which materially adversely affects the rights of the other Party hereunder. All required insurance policies of each Party must have a minimum "A-" AM Bests rating.

## **15. TERM AND TERMINATION.**

**15.1 Term.** The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until the expiration of the last Agreement Payment Term in the Territory, unless terminated earlier by either Party pursuant to this Article 15 or by written agreement of the Parties ("**Term**").

**15.2 Termination for Material Breach.** Either Party may terminate this Agreement if the other Party commits a breach of its material obligation under this Agreement, and such material breach is not cured by the breaching Party within [\*\*\*\*\*] after the breaching Party's receipt of written notice thereof from the non-breaching Party.

**15.3 Termination for Insolvency.** If, at any time during the Term, (a) a case is commenced by or against either Party under Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States (the "**Bankruptcy Code**") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within [\*\*\*\*\*] after the commencement thereof, (b) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) either Party assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for either Party's business, or (e) a substantial portion of either Party's business is subject to attachment or similar process (each of ((a) through (e)), a "**Bankruptcy Event**"); then, in any case of a Bankruptcy Event, the other Party may terminate this Agreement immediately upon written notice to the extent permitted under Applicable Law. All rights and licenses granted under or pursuant to this Agreement by each Party to the other Party, as applicable, are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101(35A) of the Bankruptcy Code. The Parties agree that each Party, as a licensee of such intellectual property rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or analogous provisions of Applicable Law outside the United States, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property rights licensed to such Party under this Agreement and all embodiments of such intellectual property rights, which, if not already in such Party's possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon such Party's written request therefor, unless the Party in the bankruptcy proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i), following the rejection of this Agreement in the bankruptcy proceeding, upon written request therefor by the other Party.

**15.4 Termination for Failure to Meet Specified Endpoints.** If the Clinical Trial involving the Artiva Product [\*\*\*\*\*] fails to (i) meet safety or tolerability endpoints or (ii) pass a futility assessment, [\*\*\*\*\*], Affirmed may terminate this Agreement upon [\*\*\*\*\*] prior written notice to Artiva. [\*\*\*\*\*].

**15.5 Effects of Termination.**

**(a) Termination of Licenses.** Upon any termination of this Agreement, the licenses granted by a Party to the other Party under Section 4.1 shall terminate as of the effective date of such termination.

**(b) Return or Destruction of Materials, Confidential Information and Artiva Products.** Upon any expiration or termination of this Agreement: (i) each Party shall return or destroy the other Party's Materials in its possession in accordance with Section 5.11(b); (ii) each Party shall return or destroy the other Party's Confidential Information in accordance with

Section 11.6; and (iii) to the extent applicable, Affimed shall return or destroy any Artiva Product in accordance with Section 11.6.

(c) **Wind Down.** Upon receipt by either Party of a termination notice of this Agreement, the Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner, including with respect to any ongoing Combination Therapy Clinical Trials. The terminating Party shall submit to the other Party, and the Parties shall discuss and agree, a proposed wind-down, setting forth the tasks reasonably necessary or required in connection with the orderly termination of any ongoing Combination Therapy Clinical Trials and the proper plan for managing the patients enrolled in such trials, including actions reasonably necessary to safely close out such trials, or required by Applicable Laws.

(d) **Survival.** Any expiration or termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such expiration or termination, has already accrued to such Party or which is attributable to a period prior to such expiration or termination. Without limiting the generality of the foregoing, the following provisions shall survive any termination or expiration of this Agreement: Article 10, Article 11, Article 12, Article 14, Article 17 and Article 18; and (ii) Section 3.1(b), Section 3.1(c), Section 4.2, Section 5.11, Sections 9.3 to 9.7 and Section 15.5.

## 16. OPT-OUT

16.1 **Opt-Out.** Either Party may opt out of the further Development and Promotion of the Combination Therapy with [\*\*\*\*\*]' prior written notice to the other Party at any time during the following periods:

(a) [\*\*\*\*\*]

(b) [\*\*\*\*\*].

### 16.2 Right to Continue Development or Promotion of the Combination Therapy.

(a) *Artiva's Right to Continue.* In case of an opt-out by Affimed pursuant to Section 16.1, Artiva shall have the right, at its election in its sole discretion, to continue Development and Promotion of the Combination Therapy in the Field in the Territory at its sole cost. [\*\*\*\*\*].

(b) *Affimed's Right to Continue.* In case of an opt-out by Artiva pursuant to Section 16.1, Affimed shall have the right, at its election in its sole discretion, to continue Development and Promotion of the Combination Therapy in the Field in the Territory at its sole cost. [\*\*\*\*\*].

## 17. DISPUTE RESOLUTION.

17.1 **Disputes.** Except as otherwise provided under Section 3.5, if the Parties, in consultation with each Party's Alliance Managers, are unable to resolve any a dispute, controversy or claim of any nature whatsoever arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, (each, a "**Dispute**"), either Party may, by written notice to the

other, have such Dispute referred to the Executive Officers of each of Artiva and Affirmed for attempted resolution by good faith negotiations within [\*\*\*\*\*] Business Days after such notice is received. In such event, the Parties shall cause their Executive Officers or their designees to meet and be available to attempt to resolve such issue. If the Parties are unable to resolve any Dispute under this Section 17.1, or if the JEC is unable to resolve any Dispute relating to any Unanimous Matter pursuant to Section 3.5, either Party shall have the right to commence arbitration as set forth in Section 17.2. Any dispute concerning the commencement of the arbitration shall be finally settled by the arbitrators.

**17.2 Arbitration.** All Disputes shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with the said Rules. The seat, or legal place of the arbitration shall be Geneva, Switzerland. The language of the arbitration shall be English. The law applicable to the substance of the Disputes is the law chosen by the Parties in Section 18.1 of this Agreement.

**17.3 Confidentiality.** Except for purposes of confirming or challenging an award, or court proceedings to obtain interim relief, any and all activities conducted under this Article 17, including any proceedings, submissions and decisions hereunder, will be deemed Confidential Information of each of the Parties, and will be subject to Article 11, to the extent applicable in accordance with Applicable Law.

**17.4 Continued Performance.** *Provided* that this Agreement has not terminated, the Parties agree to continue performing under this Agreement in accordance with its provisions, pending the final resolution of any Dispute.

## **18. GENERAL PROVISIONS.**

**18.1 Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Agreement.

**18.2 Assignment.** Neither Party may assign or otherwise transfer, in whole or in part, this Agreement without the prior written consent of the other Party, such approval not to be unreasonably withheld or delayed. Notwithstanding the foregoing, either Party may assign this Agreement, in whole or in part, without the other Party's prior written consent, to (a) an Affiliate or (b) to a successor in interest by way of merger, consolidation or sale of all or substantially all of the assets of such Party to which this Agreement relates. This Agreement may only be assigned together with the Related Agreements. Any attempted assignment of this Agreement not in compliance with this Section 18.2 shall be null and void. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. This Agreement shall inure to the benefit of and be binding upon each Party, its successors and permitted assigns.

**18.3 Use of Name.** Except as expressly provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the



performance of this Agreement. Notwithstanding the foregoing, consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences or symposia relating to the Combination Therapy Trials which disclose the name of a Party, *provided* that such use does not constitute an endorsement of any commercial product or service by the other Party.

**18.4 Force Majeure.** Neither Party shall be liable to the other Party for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, terrorist acts, strike, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the affected Party, and occurring without the affected Party's fault or negligence. The Party affected by such force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable.

**18.5 Severability.** If any provision of this Agreement is found by a court of competent jurisdiction to be unenforceable, then such provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of this Agreement. The remainder of this Agreement will remain in full force and effect, unless the severed provision is essential and material to the rights or benefits received by either Party. In such event, the Parties will negotiate, in good faith, and substitute a valid and enforceable provision or agreement that most nearly implements the Parties' original intent in entering into this Agreement.

**18.6 Waiver.** No failure or delay of a Party to insist upon strict performance of any of its rights or powers under this Agreement shall operate as a waiver thereof, nor shall any other single or partial exercise of such right or power preclude any other further exercise of any rights or remedies provided by law. No waiver by a Party of a particular provision, right or remedy shall be effective unless in writing and signed by an authorized representative of such Party.

**18.7 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall make specific reference to this Agreement and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 18.7, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable overnight delivery service, (b) on the day of sending by facsimile or email (with documented confirmation of receipt), if followed by mailing by first class certified or registered mail, postage prepaid, return receipt requested or sent by a reputable overnight delivery service or (c) five (5) days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested.

If to Artiva, to:

Artiva Biotherapeutics, Inc.  
5505 Morehouse Drive, Suite 100  
San Diego, CA 92121, USA  
Attn: [\*\*\*\*\*]  
Email: [\*\*\*\*\*]

If to Affimed, to:

Affimed GmbH  
Im Neuenheimer Feld 582  
69120 Heidelberg, Germany  
Attn: [\*\*\*\*\*]  
Email: [\*\*\*\*\*]

**18.8 Relationship of the Parties.** The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. The Parties do not intend this Agreement or the transactions and obligations contemplated herein to constitute a partnership for any US federal or applicable state, local or non-U.S. income tax purposes. Neither Party shall have the authority to make any statements, representations or commitments of any kind, enter into contracts or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

**18.9 Further Assurance.** Each Party shall, and shall use all reasonable endeavors to procure that any necessary Third Party shall, promptly execute and deliver such further documents and do such further acts as may be required for the purpose of giving full effect to this Agreement.

**18.10 Injunctive Relief.** Each Party hereby acknowledges and agrees that in the event of the other Party's actual or threatened breach of any provision of this Agreement relating to the Materials, Confidential Information and/or intellectual property rights (including, Section 5.11, Article 10 and Article 11), the non-breaching Party would suffer an irreparable injury such that no remedy at law would adequately protect or appropriately compensate the non-breaching Party for such injury. Accordingly, notwithstanding anything to the contrary provided in this Agreement, each Party agrees that the non-breaching Party shall have the right to enforce this Agreement and any of such provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the non-breaching Party may have for a breach of this Agreement.

**18.11 Headings; Interpretation.** The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Articles, Sections and Exhibits hereto. Unless context otherwise clearly

requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (b) the word “day” or “year” means a calendar day or year unless otherwise specified; (c) the word “will” shall be construed to have the same meaning and effect as the word “shall” wherever context requires; (d) the words “hereof,” “herein,” “hereby” or other similar words refer to this Agreement (including any Exhibits); (e) the word “or” shall be construed as the inclusive meaning identified with the phrase “and/or”; (f) words of any gender include the other gender; (g) words using the singular or plural number also include the plural or singular number, respectively; (h) references to any Applicable Law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement Applicable Law thereto; and (i) neither Party or its Affiliates shall be deemed to be acting “on behalf of” or “under authority of” the other Party under this Agreement. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

**18.12 No Third Party Beneficiaries.** This Agreement is for the sole benefit of the Parties hereto and their permitted assigns. Nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever, under or by reason of this Agreement.

**18.13 Entire Agreement; Amendment.** This Agreement (together with all Exhibits attached hereto and the Related Agreements, each of which is incorporated herein by this reference) constitutes the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements, negotiations, arrangements and understandings, both written and oral, between the Parties with respect to the subject matter hereof. For clarity, this Agreement supersedes Section 5.5 and Section 5.7 of the Prior Collaboration Agreement solely as applicable to the Joint Background Patents. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless in writing and signed by the respective authorized officers of the Parties.

**18.14 Counterparts; Electronic Signatures.** This Agreement may be executed in two or more counterparts (whether delivered by email via .PDF format, facsimile or otherwise), each of which will be considered one and the same agreement and will become effective when counterparts have been signed by each of the Parties and delivered to the other Party. This Agreement may be executed by signatures on an electronic image (such as .PDF or .JPG format) and electronic signatures, all of which shall have the same force and effect as original signatures.

*[Signature page follows]*

IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

**AFFIMED GMBH**

**ARTIVA BIOTHERAPEUTICS, INC.**

By: /s/ Adi Hoess  
Name: Dr. Adi Hoess  
Title: CEO

By: /s/ Fred Aslan  
Name: Dr. Fred Aslan  
Title: CEO

By: /s/ Wolfgang Fischer  
Name: Dr. Wolfgang Fischer  
Title: COO

**SIGNATURE PAGE TO COLLABORATION AGREEMENT**

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## **Exhibit 1.9**

### **Affimed Product**

The tetravalent antibody construct bispecific for CD30 and CD16A that specifically targets CD30 on Hodgkin lymphoma cells and other lymphomas, and recruits and activates CD16A-positive innate immune cells, such as natural killer cells, referred to by Affimed as AFM13.

Exhibit 1.21

Existing Artiva Background Patents

<b>Title</b>	<b>Application No.</b>	<b>Filing Date</b>
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]

**Exhibit 1.24**

**Artiva Product**

A non-genetically modified, ex-vivo expanded, umbilical cord blood-derived, allogeneic NK cell therapy referred to by Artiva as AB-101.



Exhibit 1.94

Joint Background Patents

<b>Title</b>	<b>Application No.</b>	<b>Filing Date</b>
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]

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CLINICAL STUDY PROTOCOL CONCEPT SHEET

- [\*\*\*\*\*]
  - [\*\*\*\*\*]
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**SPONSOR SIGNATORY**

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**1. OVERALL RATIONALE FOR THE STUDY**

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2. [\*\*\*\*]

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**Table 1:** [\*\*\*\*]

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**Table 2:** [\*\*\*\*\*]

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3. [\*\*\*\*]

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**Exhibit 5.3(c)**  
**Responsibility Matrix**

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## Exhibit 9.2(c)

### Baseball Arbitration

If the Parties cannot agree, following escalation to the Executive Officers, on the Agreement Payment pursuant to Section 9.2(c) (such dispute, an “*Expert Matter*”), at the request of either Party by written notice to the other Party, such Expert Matter will be resolved through binding “baseball” arbitration pursuant to this Exhibit 9.2(c) rather than pursuant to the procedures under Section 17.2. If the Expert Matter is not resolved within [\*\*\*\*\*] after referral to the Parties’ Executive Officers, then either Party may send the other Party a written notice requesting to resolve the Expert Matter by using an independent investment banker who shall have no less than ten (10) years of experience in the biotechnology or pharmaceutical industry and relevant expertise and experience with respect to the Expert Matter (“*Expert*”) and shall be selected by mutual agreement of the Parties. If the Parties are unable to agree upon an Expert within [\*\*\*\*\*] after a Party gives the written notice requesting expert resolution, then each Party will have [\*\*\*\*\*] to choose a single independent expert meeting the Expert criteria, and the Parties shall instruct such experts to use best efforts to mutually select, within [\*\*\*\*\*] following the selection of the second of such experts, an independent third expert who meets such criteria to be the Expert. Within [\*\*\*\*\*] after appointment of the Expert, each Party shall submit to the Expert, with a copy to the other Party, one (1) proposal for resolving the applicable Expert Matter, including the proposed Agreement Payment and a reasonably detailed analysis of the model prepared by such Party taking into account the factors described in Section 9.2(c) to determine the proposed Agreement Payment. The Expert will be instructed to select one Party’s proposal no later than [\*\*\*\*\*] following the receipt of both Parties’ proposals and to select the proposal that he or she determines is the most commercially reasonable under the circumstances and best gives effect to the intent of the Parties to effect the Agreed Value under this Agreement. The Expert shall select only one (1) of the proposals submitted by the Parties (without making any changes to such proposal) and shall render such proposal as the Expert’s final decision. Notwithstanding anything to the contrary in this Agreement, the Expert shall not have the authority to render any decision other than selecting one (1) proposal submitted by a Party pursuant to this Exhibit 9.2(c). The Expert’s decision shall be final and binding on the Parties. The out-of-pocket costs of the Expert in making the determination pursuant to this Exhibit 9.2(c) shall be shared equally by the Parties, regardless of the outcome of the determination. All activities undertaken by the Expert will be conducted subject to obligations of confidentiality no less restrictive than those set forth in Article 11. Further, the Parties acknowledge and agree that their respective proposals and all information exchanged in connection with the expert proceedings, and the conduct of such proceedings and any information produced thereunder shall be Confidential Information under this Agreement and subject to the provisions of Article 11.



**Affimed and Artiva Biotherapeutics Announce Partnership to Advance Combination Therapy of Innate Cell Engager (ICE®) AFM13 and Off-the-Shelf Allogeneic NK Cell Therapy AB-101**

- Companies to combine their clinical programs (AFM13, AB-101) to address high unmet need of CD30-positive lymphoma patients
- Affimed's AFM13 in combination with cord blood-derived NK cells demonstrated exceptionally high response rates in relapsed and refractory CD30-positive lymphoma patients
- AB-101 is a clinical-stage, cryopreserved, off-the shelf, non-genetically modified, allogeneic cord blood-derived NK cell manufactured at large scale via Artiva's AlloNK™ platform as a universal ADCC-enhancing cell therapy
- In preclinical studies, the combination of AFM13 and AB-101 demonstrated potent anti-tumor activity
- An investigational new drug (IND) submission to the U.S. Food and Drug Administration (FDA) is planned for the first half of 2023
- Affimed to receive 67% of the combination therapy revenues, and Artiva to receive 33%
- Companies to host conference call/webcast later today at 10:30 am EDT

**San Diego and Heidelberg, Germany, November X, 2022** – Affimed N.V. (Nasdaq: AFMD) ("Affimed"), and Artiva Biotherapeutics Inc. ("Artiva"), both immuno-oncology companies focused on developing and commercializing therapies utilizing the innate immune system, today announced a new strategic partnership to jointly develop, manufacture, and commercialize a combination therapy comprised of Affimed's Innate Cell Engager (ICE®) AFM13 and Artiva's cord blood-derived, cryopreserved off-the-shelf allogeneic NK cell product candidate, AB-101.

Affimed submitted a pre-IND meeting request for the AFM13 and AB-101 combination to the FDA requesting feedback on the clinical trial design in relapsed/refractory (r/r) Hodgkin lymphoma (HL) with an exploratory arm evaluating the combination in selected subtypes of r/r CD30-positive peripheral T-cell lymphoma (PTCL) and potential path to registration. FDA responded to this request and guided to providing feedback by Q1 2023.

This clinical agreement follows the parties' existing two-year preclinical collaboration to assess combining elements of the companies' respective platforms in the generation of targeted, off-the-shelf allogeneic NK cell therapies.

"Based on the compelling clinical data we have generated for AFM13 in combination with NK cells, we are committed to finding the fastest path to bringing this potentially life-changing treatment to lymphoma patients," said Dr. Adi Hoess, CEO of Affimed. "The allogeneic NK field is still at a nascent stage, and we selected Artiva because of their commercially-viable production process that can support a multicenter clinical trial and potentially enable a path to registration."

"We are developing AB-101 as a universal ADCC enhancer when combined with monoclonal antibodies and NK cell engagers," said Dr. Fred Aslan, CEO of Artiva. "The data Affimed has generated to date with AFM13 in combination with cord blood-derived NK cells in a patient population with great unmet need is very compelling, and we are excited to partner with Affimed on what could become one of the first approvals for an allogeneic NK cell therapy-based regimen."

AFM13 is currently being investigated in combination with allogeneic cord blood-derived NK cells (CBNK) in an investigator-sponsored study together with The University of Texas MD Anderson Cancer Center. Data from this study published earlier today for presentation at the 64th ASH Annual Meeting and Exposition demonstrated that all 24 patients in the recommended Phase 2 dose cohort responded (overall response rate of 100%) and showed a complete response rate of 70.8%. The combination was well tolerated with few infusion-related reactions and without cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft versus host disease.

The Affimed-Artiva partnership aims to expedite further development of the combination therapy in CD30-positive lymphoma patients who have exhausted other treatment options. AB-101 has already completed a monotherapy safety cohort in an initial Phase 1 trial and is currently being assessed in combination with the anti-CD20 monoclonal antibody, rituximab, in patients with relapsed or refractory non-Hodgkin lymphoma (NHL). Preclinical results investigating the combination of AFM13 and AB-101 have further demonstrated enhanced anti-tumor activity. The companies plan to file an IND for the program in relapsed/refractory CD30-positive lymphoma patients during the first half of 2023.

Under the terms of the agreement, Affimed and Artiva will pursue the development of the AFM13/AB-101 combination treatment in the United States on a co-exclusive basis. Affimed will lead regulatory activities through the Phase 2 and any confirmatory studies. Affimed will be responsible for funding clinical study costs through Phase 2, while Artiva will be responsible for the costs of supplying AB-101 and IL-2 for such studies. Following a potential accelerated approval, the companies will share confirmatory study costs on a 50/50 basis. Both companies will retain commercialization and distribution rights and book sales for their respective products. Affimed will be responsible for promotional activities and expenses of the combination therapy. Pursuant to the agreement, revenues from the combination will be shared, with Affimed receiving 67% of the combination therapy revenue and Artiva receiving 33%.

#### **Conference Call/Webcast Details**

<To be inserted when available>

#### **About AFM13**

AFM13 is a first-in-class innate cell engager (ICE®) that uniquely activates the innate immune system to destroy CD30-positive hematologic tumors. AFM13 induces specific and selective killing of CD30-positive tumor cells, leveraging the power of the innate immune system by engaging and activating natural killer (NK) cells and macrophages. AFM13 is Affimed's most advanced ICE® clinical program and is currently being evaluated as a monotherapy in a registration-directed trial in patients with relapsed/refractory peripheral T-cell lymphoma or transformed mycosis fungoides (REDIRECT). Additional details can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04101331).

#### **About AB-101**

AB-101 is a cord blood-derived, allogeneic, cryopreserved, ADCC-enhancing NK cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers. Artiva selects cord blood units with the high affinity variant of the receptor CD16 and a KIR-B haplotype for enhanced product activity. Artiva can generate thousands of doses of pure, cryopreserved, infusion-ready NK cells from a single umbilical cord blood unit while retaining the high and consistent expression of CD16 without the need for engineering. Artiva is conducting a Phase 1/2 multicenter clinical trial (ClinicalTrials.gov Identifier: NCT04673617) to assess the safety and clinical activity of AB-101 alone and in combination with the anti-CD20 monoclonal antibody, rituximab, in patients with relapsed or refractory B-cell-non-Hodgkin lymphoma (NHL) who have progressed beyond two or more prior lines of therapy.

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

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to give 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).

#### **About Artiva**

Artiva's mission is to deliver highly effective, off-the-shelf, allogeneic NK cell-based therapies utilizing our Manufacturing-First approach, that are safe and accessible to cancer patients. Artiva's pipeline includes AB-101, an ADCC enhancer NK-cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers. Artiva is currently advancing a

Phase 1/2 clinical trial of AB-101 in combination with rituximab for the treatment of relapsed or refractory B-cell lymphomas. Artiva's pipeline also includes AB-201, an anti-HER2 CAR-NK cell therapy candidate for the treatment of HER2-overexpressing tumors, such as breast, gastric, and bladder cancers, and for which an IND has been allowed by FDA, and a pipeline of CAR-NK candidates targeting both solid and hematopoietic cancers. Artiva has entered into therapeutic NK cell collaborations with Merck Sharp & Dohme Corp. and with Affimed GmbH. Artiva's AlloNK™ platform incorporates cell expansion, activation, and engineering technology developed by Artiva's strategic partner, GC Cell Corporation, a member of the GC family of companies, a leading healthcare company in Korea. Artiva is headquartered in San Diego. For more information, please visit [www.artivabio.com](http://www.artivabio.com).

**Affimed Investor Relations Contact**

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**Continuation Regime Affirmed Opt-Out**

**1.1** The Parties shall in good faith agree on a transition plan and timeline to transition into the set-up provided in this Exhibit 16.2(a).

**1.2** Subject to the further provisions of this Exhibit 16.2(a), Artiva shall have the right to perform all Development and regulatory activities regarding the Combination Therapy in the Territory that are allocated to Affirmed pursuant to this Agreement and the Development Plan, at Artiva's sole cost, with the relevant provisions of Articles 5 and 6 (other than the sharing of costs for the Confirmatory Therapy Trial Activities) and Section 12.2(a) applied *vice versa* (i.e. [\*\*\*\*\*]). The Parties shall amend the Development Plan (and the responsibility matrix in Exhibit 5.3(c)) [\*\*\*\*\*], whereas the activities and responsibilities allocated to Affirmed in the Development Plan as of the effective date of the opt-out shall be (at maximum) equivalent in scope to the activities allocated to Artiva in the Development Plan (and the responsibility matrix in Exhibit 5.3(c)) before the effective date of the opt-out (i.e., supplying sufficient quantities of Affirmed Products and limited consultancy support).

**1.3** The JSC shall be dissolved and any remaining alignment on Development and regulatory activities shall be handled through the Alliance Managers, [\*\*\*\*\*]. Artiva shall have the final decision-making authority except with respect to Unanimous Matters which shall be amended and limited to the following:

**1.3.1** expand or add any obligations of Affirmed, including any costs incurred by Affirmed, beyond what Affirmed has otherwise agreed in writing;

**1.3.2** amend or change the Development Plan to include additional Indications;

**1.3.3** decide any aspect of any Protocol, Regulatory Materials or strategy therefor, or make any other decision, in each case to the extent that it relates to the Affirmed Product (including as part of the Combination Therapy), [\*\*\*\*\*];

**1.3.4** approving statements within Promotional Materials to the extent they are relating to the Affirmed Product (e.g., relating to its efficacy, safety or use) as a monotherapy or as part of the Combination Therapy (and not the Artiva Product); and

**1.3.5** determining or modifying the In-Scope Adjusted Revenue Tracking Methodology, Demand Projections or Clinical Demand Plan, or modifying the Royalty Payments.

**1.4** [\*\*\*\*\*].

**1.5** [\*\*\*\*\*]:

**1.5.1** [\*\*\*\*\*]

**1.5.2** [\*\*\*\*\*].

**1.6** [\*\*\*\*\*].

**1.7** The exclusivities according to Section 4.3(b) and 4.3(c) shall terminate, but the exclusivities according to Section 4.3(a) (subject to the exceptions according to Section 4.3(d)) shall survive for the remaining term of the Agreement.

**1.8** Artiva shall be solely responsible for all costs associated with the Development of the Combination Therapy (including, for clarity, all costs associated with all Combination Therapy Trials, including the Confirmatory Combination Therapy Trial) in accordance with this Agreement and the Development Plan (as amended according to para. 1.2). [\*\*\*\*\*].

**1.9** [\*\*\*\*\*].

**1.10** Affimed shall transfer and assign all Regulatory Materials and Regulatory Approvals for the Combination Therapy in its Control to Artiva. Artiva hereby grants Affimed a “right of reference” (as defined in 21 C.F.R. §314.3(b)), or similar “right of reference” as defined in applicable regulations in the relevant jurisdiction, with respect to any Regulatory Materials for the Combination Therapy in the Territory and the Combination Therapy Clinical Data contained therein solely (i) to the extent necessary for Affimed to apply for, obtain and maintain Regulatory Approvals for the Affimed Product either as a monotherapy or in combination with, or as part of a combination therapy with, agents or products other than the Artiva Product, provided that Affimed shall not have any right of reference with respect to any Regulatory Materials for the Combination Therapy in the Territory and the Combination Therapy Clinical Data contained therein for any combination with an NK cell other than the Artiva Product, and (ii) for inclusion in the safety database for the Affimed Product. The “right of reference” granted by Affimed to Artiva according to Section 6.3(b) shall remain in full force and effect without modification; for the avoidance of doubt, also after the effective date of the opt-out, Artiva shall not have any right of reference with respect any Regulatory Materials for the Combination Therapy in the Territory and the Combination Therapy Clinical Data contained therein for any combination with an Innate Cell Engager Technology other than the Affimed Product.

**1.11** Should Affimed at any time before market launch of the Affimed Product in the Territory decide (in its free discretion) to cease any Development or regulatory activities required for such market launch, then Affimed shall not be in breach of its respective performance obligations (including its Commercially Reasonable Efforts obligations according to Section 5.2 or 6.2(c)), and upon Artiva’s written request, the Parties shall negotiate in good faith the grant of a license by Affimed to Artiva relating to the Affimed Product for the Combination Therapy in the Territory.

**1.12** The Parties shall amend the Quality Agreement and Pharmacovigilance Agreement to reflect the opt-out and the [\*\*\*\*\*] as set forth in this Exhibit 16.2(a).

**1.13** Artiva shall be solely responsible for Promoting the Combination Therapy following the effective date of the opt-out at its own cost and in accordance with the applicable Regulatory Approval for the Combination Therapy. Artiva shall assume all rights and responsibilities of Affimed in respect of the Promotion of the Combination Therapy and any

Promotional Materials according to Article 7; *provided* that the JCC shall be dissolved, Sections 3.3, 7.2 and 7.4 shall terminate and be of no force and effect, and any (remaining) alignment with Affimed on the Promotion of the Combination Therapy and any Promotional Materials shall be limited to aspects relating to the Affimed Product (including statements in any Promotional Materials relating to the Affimed Product (e.g., relating to its efficacy, safety or use) which shall require Affimed's approval). Each Party shall continue to be responsible for the Commercialization, filling of orders and booking of sales and revenue for its Product.

**1.14** [\*\*\*\*\*].

**1.15** [\*\*\*\*\*].

**1.16** Article 10 shall continue to apply after the effective date of the opt-out, except that [\*\*\*\*\*].

**Exhibit 16.2(b)**

**Continuation Regime Artiva Opt-Out**

**1.1** The Parties shall in good faith agree on a transition plan and timeline to transition into the set-up provided in this Exhibit 16.2(b).

**1.2** The JSC shall be dissolved and any remaining alignment on Development and regulatory activities shall be handled through the Alliance Managers, [\*\*\*\*\*]. Affimed shall have the final decision-making authority except with respect to Unanimous Matters which shall be amended and limited to the following:

**1.2.1** expand or add any obligations of Artiva, including any costs incurred by Artiva, beyond what Artiva has otherwise agreed in writing;

**1.2.2** amend or change the Development Plan to include additional Indications;

**1.2.3** decide any aspect of any Protocol, Regulatory Materials or strategy therefor, or make any other decision, in each case to the extent that it relates to the Artiva Product (including as part of the Combination Therapy), [\*\*\*\*\*];

**1.2.4** approving statements within Promotional Materials solely to the extent they are relating to the Artiva Product (e.g., relating to its efficacy, safety or use) as a monotherapy or as part of the Combination Therapy (and not the Affimed Product); and

**1.2.5** determining or modifying the In-Scope Adjusted Revenue Tracking Methodology, Demand Projections or Clinical Demand Plan, or modifying the Royalty Payments.

**1.3** Section 4.2 of the Agreement remains in full force and effect without modification.

**1.4** [\*\*\*\*\*].

**1.5** [\*\*\*\*\*].

**1.6** Should Artiva at any time before market launch of the Artiva Product in the Territory decide (in its free discretion) to cease any Development or regulatory activities required for such market launch, then Artiva shall not be in breach of its respective performance obligations (including its Commercially Reasonable Efforts obligations according to Section 5.2 or 6.2(a)), and upon Affimed's written request, the Parties shall negotiate in good faith the grant of a license by Artiva to Affimed relating to the Artiva Product for the Combination Therapy in the Territory.

**1.7** [\*\*\*\*\*].

**1.8** [\*\*\*\*\*].

**1.9** Section 9.2 shall continue to apply, with the Agreed Value pursuant to Section 9.2(c) to be [\*\*\*\*\*].

## CERTIFICATION

I, Adi Hoess, certify that:

1. I have reviewed this annual report on Form 20-F of Affimed N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 23, 2023

/s/ Adi Hoess

\_\_\_\_\_  
Name: Adi Hoess

Title: Chief Executive Officer

(Principal Executive Officer)

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## CERTIFICATION

I, Angus W. Smith, certify that:

1. I have reviewed this annual report on Form 20-F of Affimed N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 23, 2023

/s/ Angus Smith

\_\_\_\_\_  
Name: Angus W. Smith

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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## CERTIFICATION

The certification set forth below is being submitted in connection with Affimed N.V.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2022 (the "**Report**") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "**Exchange Act**") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Adi Hoess, the principal executive officer of Affimed N.V., certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Affimed N.V.

Date: March 23, 2023

/s/ Adi Hoess

\_\_\_\_\_  
Name: Adi Hoess

Title: Chief Executive Officer

(Principal Executive Officer)

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## CERTIFICATION

The certification set forth below is being submitted in connection with Affimed N.V.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2022 (the "**Report**") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "**Exchange Act**") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Angus W. Smith, the principal financial and accounting officer of Affimed N.V., certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Affimed N.V.

Date: March 23, 2023

/s/ Angus Smith

\_\_\_\_\_  
Name: Angus W. Smith

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements on Form S-8 (No. 333-198812) and Form F-3 (No. 333-260946 and No. 333-251648) of our reports dated March 23, 2023, with respect to the consolidated statements of Affimed N.V. and the effectiveness of internal control over financial reporting.

Mannheim, Germany  
March 23, 2023

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