

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
**FORM 20-F**

(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, 2015

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)*

**The Netherlands**

*(Jurisdiction of incorporation or organization)*

**Technologiepark, Im Neuenheimer Feld 582**

**69120 Heidelberg, Germany,**

**(+49) 6221-65307-0**

*(Address of principal executive offices)*

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*(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)*

*Copies to:*

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**New York, NY 10017**

**Phone: (212) 450-4000**

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

**Title of each class**

Common shares, nominal value €0.01 per share

**Name of each exchange on which registered**

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)

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: 33,259,404

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes  No (not required)

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

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**

TandAb® is our registered trademark. The trademarks, trade names and service marks appearing in this Annual Report are property of their respective owners.

## FORWARD-LOOKING STATEMENTS

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 limited operating history and a history of operating losses; as of December 31, 2015, our accumulated deficit was €120.2 million;
- § the chance our clinical trials may be delayed or not be successful and clinical results may not reflect results seen in previously conducted 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 AFM11, which are still in clinical development and may eventually prove to be unsuccessful;
- § uncertainty surrounding whether the clinical development steps up to commercialization will gain regulatory approval;
- § the outcome of any, or any discussions we may enter regarding, acquisitions, dispositions, partnerships, license transactions or changes to our capital structure, including 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;
- § 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 the DKFZ, Xoma, LLS, Amphivena and Amphivena’s other investors and partners, including MPM Capital, Aeris Capital and Janssen, Merck, and the potential failure to enter into new strategic relationships;
- § 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;

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- § our ability to scale-up manufacturing processes of our product candidates and also to reduce the cost of manufacturing our product candidates in advance of any commercialization;
- § our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and
- § other risk factors discussed under “Item 3. Key Information—D. Risk factors.”

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

## 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. Selected Financial Data

The comprehensive loss and financial position data for the years ended December 31, 2012, 2013, 2014 and 2015 of Affimed N.V. are derived from our consolidated financial statements. We maintain our books and records in euros, and we prepare our financial statements under International Financial Reporting Standards as issued by the International Accounting Standards Board (“IFRS”).

Financial information presented in the consolidated financial statements of Affimed N.V. for periods prior to the corporate reorganization on September 17, 2014 is that of Affimed Therapeutics AG, Heidelberg, Germany, and its subsidiary.

This financial information should be read in conjunction with “Item 5—Operating and Financial Review and Prospects” and our consolidated audited financial statements, including the notes thereto, included in this Annual Report.

**Consolidated Statements of Comprehensive Loss Data**  
For the years ended December 31,

(in thousands of € except for per share data)	2012	2013	2014	2015
<b>Revenue</b>	<b>1,173</b>	<b>5,087</b>	<b>3,382</b>	<b>7,562</b>
Other income/(expenses)—net	206	610	381	651
Research and development expenses	(8,726)	(14,354)	(9,595)	22,008
General and administrative expenses	(3,050)	(7,046)	(2,346)	7,548
<b>Operating loss</b>	<b>(10,397)</b>	<b>(15,703)</b>	<b>(8,178)</b>	<b>(21,343)</b>
<b>Finance income/(costs)—net</b>	<b>(3,926)</b>	<b>(10,397)</b>	<b>7,753</b>	<b>1,104</b>
<b>Loss before tax</b>	<b>(14,323)</b>	<b>(26,100)</b>	<b>(425)</b>	<b>(20,239)</b>
Income taxes	9	1	166	0
<b>Loss for the period</b>	<b>(14,314)</b>	<b>(26,099)</b>	<b>(259)</b>	<b>(20,239)</b>
<b>Total comprehensive loss</b>	<b>(14,314)</b>	<b>(26,099)</b>	<b>(259)</b>	<b>(20,239)</b>
<b>Loss per share in € per share</b>	<b>(0.97)</b>	<b>(1.76)</b>	<b>(0.01)</b>	<b>(0.71)</b>

(in thousands of €)	As of December 31,			
	2012	2013	2014	2015
Cash and cash equivalents	4,902	4,151	39,725	76,740
Total assets	7,191	6,500	41,909	79,322
Total liabilities	80,815	105,723	10,114	12,048
Accumulated deficit	(73,631)	(99,730)	(99,989)	(120,228)
Total equity	(73,124)	(99,223)	31,795	67,274

### Exchange Rate Information

Our business is primarily conducted in the European Union, and we maintain our books and records in euros. We have presented results of operations in euros.

In this Annual Report, translations from euros to U.S. dollars (and vice versa):

- § relating to payments made on or before December 31, 2015 were made at the rate in effect at the time of the relevant payment; and
- § relating to future payments were made at the rate of €0.919 to \$1.00, the official exchange rate quoted as of December 31, 2015 by the European Central Bank.

Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of euros at the dates indicated.

The following table presents information on the exchange rates between the euro and the U.S. dollar for the periods indicated using the rates provided by the European Central Bank:

	Period-end	Average for		
		period	Low	High
	(€ per U.S. dollar)			
<b>Year Ended December 31:</b>				
2011	0.773	0.718	0.672	0.776
2012	0.758	0.778	0.743	0.827
2013	0.725	0.753	0.724	0.783
2014	0.824	0.754	0.717	0.824
2015	0.919	0.902	0.830	0.948
<b>Month Ended:</b>				
September 30, 2015	0.893	0.891	0.876	0.898
October 31, 2015	0.908	0.890	0.874	0.915
November 30, 2015	0.945	0.932	0.907	0.945
December 31, 2015	0.919	0.919	0.910	0.943
January 31, 2016	0.916	0.921	0.914	0.930
February 29, 2016	0.918	0.901	0.884	0.919
March 2016 (through March 24, 2016)	0.897	0.904	0.884	0.921

### 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 “Forward-Looking Statements.” 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.**

***All of 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-Institut, or PEI, 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 trials 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 trials, 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 research approvals 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 trials 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 trials;
- § regulatory agencies may not find the data from preclinical studies and clinical trials sufficient or well-controlled;

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§ 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 regulations.

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.

We have no history of conducting large-scale or pivotal clinical trials or 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, AFM11 and our other product candidates. We have not yet demonstrated an ability successfully to complete a large-scale or pivotal clinical trial, 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 trials 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 our receipt of any product revenue.

A phase 2a clinical trial of AFM13 in patients with Hodgkin Lymphoma, or HL, started recruitment in the second quarter of 2015. We expect interim data in the second quarter of 2016 and primary endpoint data by the end of 2016. In addition we are also supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University for which Columbia submitted an IND to the FDA that has since become effective. We are also planning to initiate a phase 1b study investigating the combination of AFM13 with Merck's anti PD-1 antibody KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with relapsed/refractory HL in the first half of 2016.

We have initiated a phase 1 clinical trial of AFM11 in patients with non-Hodgkin Lymphoma, or NHL, and expect to report first data by the end of 2016. A phase 1 clinical trial of AFM11 in patients with acute lymphocytic leukemia, or ALL, is planned to commence in the first half of 2016. The commencement of these planned clinical trials could be substantially delayed or prevented by several factors, including:

- § further discussions with the FDA, the EMA, the PEI or other regulatory agencies regarding the scope or design of our clinical trials;
- § the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- § any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- § inability to obtain sufficient funds required for a clinical trial;
- § clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- § delay or failure in the testing, validation, manufacture and delivery of sufficient supplies of product candidate for our clinical trials;
- § delay or failure to reach agreement on acceptable clinical trial 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 trial at a prospective site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

- § slower than expected rates of patient recruitment and enrollment;
- § failure of patients to complete the clinical trial or return for post-treatment follow-up;
- § unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- § lack of efficacy during clinical trials;
- § termination of our clinical trials by one or more clinical trial sites;
- § inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- § inability to monitor patients adequately during or after treatment by us and/or our CROs; and
- § the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements and guidance as well as changes in the competitive environment may also occur and we may need to significantly amend clinical trial protocols or submit new clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, the PEI, other regulatory authorities, the IRB or ethics committee overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

- § failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- § unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- § lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- § 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.

Any failure or significant delay in completing clinical trials 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 trials 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 trials 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 trials 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 trials 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 trials will be successful because product candidates in later-stage clinical trials 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 trials. Product candidates that have shown

promising results in early clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial 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 trials, even after obtaining promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial 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 trial participants. We do not know whether any phase 2, phase 3 or other clinical trials 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.

Further, our product candidates may not be approved even if they achieve their primary endpoints in phase 3 clinical trials 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 studies and clinical trials. For example, the FDA has communicated to us that it may require us to conduct an additional dose-response trial with respect to AFM13 prior to the entry into pivotal studies, depending on data we have generated with AFM13 at that point in time. 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 trial. 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 trials. 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 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 product candidates in development are based on new technologies, such as NK-cell TandAbs, T-cell TandAbs and Trispecific Abs. The approval of our product candidates is less certain than 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, in particular regarding cytotoxicity, have yet to be developed, and the FDA, EMA or other regulatory authorities may require additional analyses to evaluate this aspect of our product quality. It is possible that the validation process may take time and resources, require independent third-party analyses or not be accepted by the FDA, the EMA and 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 continual regulatory review.***

If marketing authorization is obtained for any of our product candidates, the product will remain subject to continual 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 trials, 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 trials 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 trials 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 plan to seek fast track designation of AFM13; and we may seek fast track designation of AFM11 and/or our other product candidates or breakthrough designation of AFM13 and/or AFM11 and/or our other product candidates. There is no assurance that the FDA will grant either such designation; and, even if it does grant either such designation to AFM13 or AFM11 or one 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.***

We plan to seek fast track of AFM13 as a monotherapy and/or as a combination therapy for patients with relapsed/refractory HL, and we may see fast track designation of AFM11 or breakthrough designation of AFM13 and/or AFM11 and/or 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 fast track product may be effective. A fast track designation provides the opportunity for more frequent interactions with the FDA, and a fast track product 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 are also eligible for accelerated approval.

The FDA has broad discretion 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, but orphan drug status may not ensure that we have market exclusivity in a particular market and there is no assurance we will be able to receive orphan drug designation for AFM11 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 another drug 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 another medicinal product 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 trial data generated in accordance with an approved paediatric 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 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 have 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 method of action of harnessing the body's immune system, especially with respect to T-cell TandAbs, is powerful and could lead to serious side effects that we only discover in clinical trials. 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 trials for AFM13 demonstrated a favorable safety profile, the results from future trials of AFM13 may not confirm these results. We have recently commenced our phase 1 clinical trial of AFM11, the primary objective of which is to assess safety. The harnessing of T-cells to kill tumors is risky and may have unintended consequences. So far we have not previously demonstrated that AFM11 is safe in humans, and we cannot predict if the ongoing phase 1 clinical trial will do so.

Furthermore, we are initially developing our product candidates for patients with HL, TCL and NHL for whom no other therapies have succeeded and survival times are frequently short. Therefore, we expect that certain patients may die during the clinical trials 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 candidates or a combination thereof.

The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in 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.

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 trials 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. Adverse events in clinical trials of our product candidates or in clinical trials 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. For example, Memorial Sloan Kettering's recent suspension of enrollment of a trial of Juno Therapeutics' therapy using T-cells reengineered with chimeric antigen receptors (CARs) against CD19-positive B-cells for aggressive NHL attracted significant negative attention (although the hold was subsequently lifted). Although the mode of action of our T-cell TandAbs differs from that of CARs, 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 approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

***We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be materially adversely affected.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. 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 trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. For example, our product candidate AFM13 has orphan drug designation for the treatment of HL, which means that the potential patient population is limited. Further, in our phase 2a clinical trial of AFM13 as well as in our phase 1b combination study of AFM13 with Merck's anti PD-1 antibody KEYTRUDA<sup>®</sup> (pembrolizumab) we plan to enroll patients with relapsed/refractory HL who have been treated with Adcetris (brentuximab vedotin), which is an even more limited population of patients. As we are developing AFM13 and AFM11 for patients for whom all other therapies have failed and who may not have long to live, patients may elect not to participate in our, or any, clinical trial. In addition, there are several other drugs potentially in development for the indications for which we may develop AFM13 and AFM11, and we may compete for patients with the sponsors of trials for those drugs. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down 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 trials may also ultimately lead to the denial of regulatory approval of 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;
- § 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 therapy or as a second- or third-line therapy for particular diseases;
- § adverse publicity about our product candidates or favorable publicity about competitive products;
- § 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.***

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 plan to contract with external manufacturers to develop a larger scale process for manufacturing AFM13 in parallel with our clinical trials of AFM13, in order to have material from such commercial scale process available for a potential pivotal phase 2b trial for patients with HL. We may not succeed in the scaling up of our process. We may need a larger scale manufacturing process for AFM11 than what we have planned, depending on the dose and regimen that will be determined in our phase 1 study. 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.
- § The process of manufacturing biologics, such as AFM13, AFM11 and our other product candidates, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling 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 of time to investigate and remedy the contamination.
- § The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, 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 in 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, including leading to significant delays in the availability of drug product for our clinical trials or the termination or hold on a clinical trial, 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 trials 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 for 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 obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

There is a large number of companies developing or marketing treatments for cancer disorders, 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 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.

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 2015 for the treatment of patients with HL at high risk of relapse or progression following autologous hematopoietic stem cell transplantation as consolidation treatment. In the European Union, Adcetris is approved for the same indications. Adcetris is currently being investigated in different settings and various combinations in HL. Recent data indicate high complete response rates when combined with ipilimumab or bendamustine in relapsed/refractory HL.

Recently, clinical phase 1 data with the anti PD-1 CPIs nivolumab and pembrolizumab in HL was published in the New England Journal of Medicine and at several conferences. This early data indicates the potential of anti PD-1 antibodies to cause high response rates in the salvage setting of HL. The FDA has granted breakthrough designation for nivolumab in relapsed/refractory HL. Phase 2 studies are reported to be ongoing with nivolumab and pembrolizumab (registrational intent). If AFM13 were to be approved for HL, we would be in competition with these therapies, as well as any other therapies or combination regimens that comprise the standard of care that AFM13 could potentially displace. Several other agents have reached proof of concept clinical trials in HL, including Afinitor® (Novartis AG), ferritarg (MABLIFE), lirilumab (Innate Pharma), panobinostat (Novartis) and lenalidomide (Celgene).

With respect to competitors for AFM11, rituximab has been approved to treat certain types of NHL in both the United States and Europe and is generally combined with a chemotherapy regimen (typically CHOP or bendamustine). Imbruvica, a small molecule drug targeting malignant B-cells, was approved by the FDA in 2013 to treat the mantle cell variant of NHL (MCL). Amgen develops cancer product candidates that work by targeting receptors both on immune cells and cancer cells, like our TandAbs. Amgen's blinatumomab, a product based on the BiTE® (bispecific T-cell engager) technology, is an antibody construct similar to AFM11 and was approved by the FDA and EMA to treat patients with relapsed and refractory Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL). MacroGenics' MGD011, a CD19xCD3 DART entered phase I in B-NHL and ALL and is being developed in partnership with Janssen Biotech. Morphosys is developing an Fc-enhanced anti-CD19 monoclonal antibody (phase II). Regeneron is developing a bispecific CD20xCD3 antibody for the treatment of NHL, which is currently in phase I. In October 2015, the FDA granted breakthrough designation to Pfizer's CD22-targeting antibody-drug conjugate inotuzumab ozogamizine for the treatment of relapsed and refractory B-ALL. A second CD19-targeting antibody-drug conjugate is being developed by Seattle Genetics and has entered phase II in NHL. Juno Therapeutics, Novartis, Bellicum, Collectis and Kite Pharma are each developing

therapies using T-cells reengineered with chimeric antigen receptors (CARs) against CD19-positive B-cells. This therapeutic approach, which utilizes a patient's own T-cells after ex-vivo genetic modification, is currently being investigated in early stage clinical trials. Although limited data are available, CAR treatments seem to result in high response rates, specifically in ALL.

We expect that our TandAb and trispecific antibody platforms will serve as the basis for future product candidates and collaborations with pharmaceutical companies. Other companies also have developed platform technologies that compete with us. For example, MacroGenics is developing its DART platform, which enables the targeting of multiple receptors or cells by using a single molecule with an antibody-like structure. Ablynx is also developing such a platform aimed at multi-receptor targeting, which to date has not reached clinical testing.

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, 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 Health Care Reform Law, 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 Health Care Reform Law also created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the Health Care Reform Law, 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 trials to demonstrate the safety, purity and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for each a 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 trial sites and patient registration for clinical trials, 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, its member states and some 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 Health Care Reform Law, 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 Health Care Reform Law 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 Health Care Reform Law 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. We also cannot predict the impact of the Health Care Reform Law on our business or financial condition as many of the Health Care Reform Law reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred.

Moreover, other legislative changes have also been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These 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.

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.

***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 trials, we cannot exclude that any claims will be brought against us or our collaborators although product liability claims by participants enrolled in our clinical trials 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 trial participants;
- § termination of clinical trial 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 currently hold €10 million in business liability insurance coverage per year in the aggregate, with a per incident limit of €5 million except for environmental liability risks, for which the per incident limit is €3 million. We also hold €5 million in clinical trial insurance for the AFM11 phase 1 clinical trial with a per incident limit of €0.5 million. Our current insurance coverage and any additional coverage for further clinical trials 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.

***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 trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

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- § 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, or natural disasters including earthquakes, typhoons, floods and fires.

### ***Exchange rate fluctuations or abandonment of the euro currency 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. We have converted into euros only the portion of the IPO proceeds and the proceeds from our follow-on offering in May and the private placement in October 2015 that will be spent in euros according to our budget. If the euro/US\$ ratio changes, we may be subject to foreign exchange-rate risk. Currently, we do not have any other exchange rate hedging measures in place. In addition, the possible abandonment of the euro by one or more members of the European Union could materially affect our business in the future. Despite measures taken by the European Union to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the European Union. The effects on our business of a potential dissolution of the European Union, the exit of one or more EU member states from the European Union or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

## 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 biopharmaceutical company with a limited operating history. We have incurred significant losses since our inception. As of December 31, 2015, our accumulated deficit was €120.2 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 trials 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 trials of AFM13 or AFM11;
- § obtaining marketing approvals for our product candidates, including AFM13 or AFM11, for which we complete clinical trials;
- § 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;
- § obtaining market acceptance of our product candidates as viable treatment options;
- § addressing any competing technological and market developments;
- § 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 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. 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 trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials 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 on acceptable terms or at all. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we anticipate that our existing cash and cash equivalents and additional budgeted revenues will enable us to fund the clinical development of AFM13 and AFM11 and a pre-clinical development of AFM21/AFM 22 and AFM 24 until the first quarter of 2018, assuming all of our programs advance as currently contemplated. 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 trials;
- § 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 a sufficient amount of product revenue 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 cause dilution to our shareholders, restrict our operations or require us to relinquish substantial rights.***

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 license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares. Debt financing, if available at all, 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. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs 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, 2015, we had €76.7 million in cash and cash equivalents. Our management will have broad discretion in the use of such cash and cash equivalents and could spend it 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 10c of the *Gewerbesteuergesetz* (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 25% 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 a qualified ownership change tax loss carry forwards, consisting of the NOLs in the same percentage as the ownership change, cannot be utilized. If the percentage of the ownership change exceeds 50%, tax loss carry forwards expire in full. To the extent that the tax loss carry forwards do not exceed hidden reserves taxable in Germany, they may be further utilized despite a qualified ownership change.

As of December 31, 2015, we had NOL carry forwards for German tax purposes of €89 million. Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c *Körperschaftsteuergesetz* or a Section 10c *Gewerbesteuergesetz* limitation. Any limitation may result in the expiration of a portion or the complete tax operating 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.

**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, including our collaboration through Amphivena and our collaborations with The Leukemia & Lymphoma Society and Merck. 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 trial 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 trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials 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.

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. Furthermore, Amphivena has entered into a warrant agreement with Janssen Biotech Inc. that gives Janssen the option to acquire Amphivena following IND acceptance by the FDA, upon predetermined terms, in exchange for payments under the warrant. If (1) Janssen does not exercise its option to purchase Amphivena or terminates the warrant early, (2) no other pharmaceutical company licenses the project for clinical development or (3) insufficient financing is obtained to finance the clinical development of Amphivena's product candidate, such facts could be viewed as having negative implications for our business and prospects. Additionally, if Amphivena does not have enough funding to pay the license and development fees due to us under the license and development agreement, there is a risk that funding will not be available to continue the development of the program. If such lack of funding exists, we may never reach IND acceptance. However if Amphivena is able to show promising data for its program, we may decide to provide financing for the program.

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 trials, the likelihood of approval by the FDA, the European Commission 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. 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 collaboration with Amphivena contains restrictions on our engaging in activities that are the subject of the collaboration with third parties for specified periods of time.

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

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials. 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 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 trials. In addition, certain clinical trials in which we are involved and which are testing our product candidates are sponsored by academic sites, known as Investigator Sponsored Trials, or ISTs. By definition, the financing, design, and conduct of the study is under the sole responsibility of the respective 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. The following studies are ISTs: AFM 13 phase 2a in HL and AFM 13 phase 1b/2a in CD30+ lymphoma. 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 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 cGCP, and other local legal requirements, e.g. data privacy, for conducting, recording and reporting clinical trials 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 cGCP 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 and expect to continue to do so for commercialization. We also contract with third parties for the manufacture and supply of compounds we are investigating in clinical trials in combination with our products. 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 and internal capacity 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 eventually to 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 to 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 the 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.

For our planned clinical development of AFM13 in combination with the anti PD-1 CPI KEYTRUDA<sup>®</sup> (pembrolizumab) we entered into an agreement with Merck pursuant to which Merck will provide us with pembrolizumab to conduct a phase 1b clinical combination trial in relapsed/refractory HL. We are dependent on Merck for this supply. In addition, if we wish to pursue further development of AFM13 in combination with pembrolizumab or any other CPI, we will need to reach an agreement with Merck or another manufacturer for such supply of pembrolizumab or another CPI, respectively. If we do not have an adequate supply and/or cannot reach an agreement with the applicable manufacturer, we may not be able to develop AFM13 in such a combination. Any future supply agreement with a manufacturer for combination trials with AFM13 could influence on 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 and, 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. Our first patent family is issued and relates to the engineered antibody format, which is called TandAb, and the methods of making or using such bispecific, tetravalent domain antibodies. This patent family will expire in 2019. The second patent family on AFM13 consists of European patents relating to the use of the specific target combination for the treatment of cancer using a bispecific molecule and will expire in 2020. Our third patent family relates to the mode of action of AFM13, the recruitment of immune effector cells via a specific receptor. This patent will expire in 2026. We also own and/or control our AFM11 patent portfolio, which includes issued patents and pending patent applications. As in the case of AFM13, our issued patent relates to the engineered antibody format and will expire in 2019. The pending patent application family claims a new TandAb structure which was specifically used in AFM11. If issued, this patent will expire in 2030.

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 reexamination 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.

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

Even after they have 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 reexamination 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.

***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. Our failure to obtain a license to any 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 would be exposed to a threat of litigation.

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;
- § 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 proceeding 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 a showing of 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's 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.

***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.

***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. This is the case under the terms of our license agreements with DKFZ and Xoma, where DKFZ and Xoma are entirely responsible for the prosecution, protection and maintenance of the licensed patents and patent applications. Neither DKFZ nor Xoma has any obligation to provide us any information with respect to such prosecution and we will not have access to any patent prosecution or maintenance information that is not publicly available. Although we monitor DKFZ's and Xoma's ongoing prosecution and maintenance of the licensed patents, if DKFZ, Xoma or 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, AFM11 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, and selling 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. For example, our TandAb technology was developed under certain patents licensed exclusively to us by DKFZ under a 2001 license agreement which was subsequently amended in 2006. Additionally, an antibody generated in the development of our TandAb candidates was developed using antibody phage display technologies licensed to us by Xoma. In each of these cases, the licensor retains their full ownership interest with respect to the licensed patent rights, and our rights to use the technologies associated with those patents and to employ the inventions claimed in the licensed patent rights are subject to the continuation of and our compliance with the terms of those licenses.

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. For example, DKFZ retains responsibility for the prosecution and maintenance of its patent rights licensed under the terms of its agreement with us, and Xoma retains the right, at its sole discretion, to enforce, maintain and otherwise protect its patent rights licensed to us pursuant to our 2006 license agreement with Xoma. 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. Our existing agreements impose, and we expect that future agreements will impose, various diligence, commercialization, milestone payment, royalty, and other obligations on us. Certain of our licenses, including each of our licenses with DKFZ and Xoma, 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, including our rights to the TandAb, Flexibody and antibody phage display technologies, in clinical trials 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.

***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 the 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 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.

***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 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 employee of us and thus not obligated to assign rights in intellectual property to us 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 defending against these claims, 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 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.

***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.

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

Approximately 45 of our personnel, including 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 (*Gesetz über Arbeitnehmererfindungen*), 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 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. However, we may not receive an extension 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 could be less than we request. If we are unable to obtain patent term extension or the term of any such extension 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.

***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 trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but 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.

### **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. The contracts with three of the four managing directors run until the end of the general meeting in 2017, the contract with Dr. Windisch runs until the end of the general meeting in 2019. We do not maintain any key man insurance for our managing directors at this time.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. 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 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 our operations.***

We have 71 personnel (64 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 members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a

disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth 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 expenditures 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 any 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. 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 trials and clinical trials 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, if any cover our common shares;
- § 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;

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- § economic and other external factors or other disasters or crises;
- § 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.

***Certain of our shareholders own a majority of our common shares and as a result will be able to exercise significant control over us, and your interests may conflict with the interests of our existing shareholders.***

A small number of shareholders own more than a majority of our outstanding common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders as a group may be in a position to determine the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the capital present or represented by independent proxy and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the election of our managing directors and supervisory directors, certain decisions relating to our capital structure, the approval of certain significant corporate transactions and amendments to our Articles of Association. To the extent that the interests of these shareholders may differ from the interests of our other shareholders, the latter may be disadvantaged by any action that these shareholders may seek to pursue. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our common shares.

***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 33,259,404 common shares outstanding as of December 31, 2015. 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 an issue 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 also entered into a registration rights agreement upon consummation of our initial public offering pursuant to which we have agreed under certain circumstances to file a registration statement to register the resale of the common shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such common shares.

On October 1, 2015, we filed a shelf registration statement on Form F-3 for the potential offer and sale by us of up to \$150 million of our common shares, senior debt securities, subordinated debt securities, warrants, purchase contracts or units and the offer and sale by certain of our shareholders of 12,985,302 of our common shares. The registration statement was declared effective by the SEC on October 23, 2015. Up to \$50 million of our common shares may be offered and sold under the 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 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 Securities and Exchange Commission (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 the 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. 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 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 an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to “emerging growth companies” will make our common shares less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an “emerging growth company,” we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an “emerging growth company” for a period of five years following the completion of our initial public offering (2019), although circumstances could cause us to lose that status earlier, including if the market value of our common shares held by non-affiliates exceeds \$700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an “emerging growth company” as of the following December 31 (our fiscal year end). We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

***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.

***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.

***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: the authorization of a class of shares that may be issued to a friendly party; staggered 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.

***Our anti-takeover provision may prevent a beneficial change of control.***

We have adopted an anti-takeover measure pursuant to which our management board may, subject to supervisory board approval but without additional shareholder approval, issue (or grant the right to acquire) cumulative preferred shares. Our management board has been authorised to, subject to supervisory board approval, issue (or grant the right to acquire) cumulative preferred shares by the general meeting of shareholders on September 12, 2014, with effect from September 17, 2014. We may issue an amount of cumulative preferred shares up to 100% of our issued capital immediately prior to the issuance of such cumulative preferred shares. In such event, the cumulative preferred shares (or right to acquire cumulative preferred shares) will be issued to a separate, newly established foundation which will be structured to operate independently of us and will act to serve the best interests of us, our associated business and all parties connected to us, by opposing any influences that conflict with these interests and threaten to undermine our continuity, independence and identity. Such a measure has the effect of making a takeover of us more difficult or less attractive and as a result, our shareholders may be unable to benefit from a change of control and realize any potential change of control premium. This may materially and adversely affect the market price of our common shares.

The cumulative preferred shares will be issued to the foundation for their nominal value, of which only 25% will be due upon issuance. The voting rights of our shares are based on nominal value and as we expect our shares to trade substantially in excess of nominal value, cumulative preferred shares issued at nominal value can obtain significant voting power for a substantially reduced price and thus be used as a defensive measure. These cumulative preferred shares will have both a liquidation and dividend preference over our common shares and will accrue cash dividends at a fixed rate. The management board may issue these cumulative preferred shares to protect us from influences that do not serve our best interests and threaten to undermine our continuity, independence and identity. These influences may include a third party acquiring a significant percentage of our common shares, our receipt of an offer for our common shares, other concentration of control over our common shares or any other form of pressure on us to alter our strategic policies or anticipation that any such events may come to exist.

***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. For example, the DCGC states that all supervisory board members need to be independent (a term that is defined in the DCGC), with the exception of one. We have more than one supervisory director that is deemed not independent under 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.

***In the past, we had identified material weaknesses in our internal control over financial reporting. If the since-implemented internal controls fail to be effective, such failure could result in material misstatements in our financial statements, cause investors to lose confidence in our reported financial and other public information and have a negative effect on 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 required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. A material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. In connection with the preparation of our financial statements for the year ended December 31, 2013, we identified material weaknesses in our internal controls related to deficiencies in the design and operating effectiveness of our internal controls, in our financial reporting processes and in our controls related to management's review of our financial results. Since the identification of the material weaknesses in internal control over financial reporting we have been implementing additional internal control over financial reporting, and no material weaknesses were identified in connection with the preparation of our financial statements for the years ended December 31, 2014 and 2015. If the since-implemented internal controls fail to be effective in the future, it could result in material misstatements in our financial statements, 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 will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for a period of five years following the completion of our initial public offering (2019). 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.

***We may be classified as a "passive foreign investment company" (a "PFIC") in 2016 or any future years. U.S. investors may suffer adverse U.S. federal income tax consequences if we are a PFIC for any taxable year.***

Under the Internal Revenue Code of 1986, as amended, 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. We believe that we were not a PFIC for U.S. federal income tax purposes for our 2015 taxable year based on (i) certain assumptions regarding the classification of our income and assets for PFIC purposes; and (ii) certain estimates as to the value of our assets, including the implied value of our assets based on our market capitalization on certain dates. However, there can be no assurance that the IRS will agree with this conclusion. In addition, whether we will be a PFIC in 2016 or any future years is uncertain because, among other things, (i) we currently own a substantial amount of passive assets, including cash, (ii) 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 (iii) a decline in our market capitalization from levels experienced in 2015 may imply a value of our assets (other than cash) that could lead us to conclude that we are a PFIC for 2016 or for a future year. Accordingly, there can be no assurance that we will not be a PFIC for 2016 or for any other future taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds common shares, we generally would 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 ceased 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. We do not intend to provide the information that would enable investors to take a qualified electing fund (“QEF”) election that could mitigate the adverse U.S. federal income tax consequences should we be classified as a PFIC.

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

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

We are a clinical-stage biopharmaceutical 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 Natural Killer cells, or NK-cells, and T-cells. Our proprietary, next-generation bispecific antibodies, which we call TandAbs because of their tandem antibody structure, are designed to direct and establish a bridge between either NK-cells or T-cells and cancer cells. Our TandAbs have the ability to bring NK-cells or T-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 TandAbs bind to their targets with high affinity and have half-lives that allow regular intravenous administration. 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.

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

We have focused our research and development efforts on five proprietary programs for which we retain global commercial rights. Because our TandAbs bind with receptors that are known to be present on a number of types of cancer cells, each of our TandAb product candidates could be developed for the treatment of several different cancers. We intend to initially develop our two clinical stage product candidates in orphan or high-medical need indications, including as a salvage therapy for patients who have relapsed after, or are refractory to, that is who do not respond to treatment with, standard therapies, which we refer to as relapsed/refractory. These patients have a 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 trials 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 are also active in preclinical development with our collaborator Amphivena Therapeutics, Inc., which Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Janssen, has an option to buy upon IND acceptance by the FDA.

Our offices and laboratories are located at the Technology Park adjacent to the DKFZ in Heidelberg, where we employ 45 personnel, approximately 70% of whom have an advanced academic degree. Including AbCheck and Affimed Inc. personnel, our total headcount is 71 (64 full time equivalents). We are led by experienced executives with a track record of successful product development, approvals and launches, specifically of biologics. Our supervisory board includes highly experienced experts from the pharmaceutical and biotech industries, with a specific background in hematology. Affimed has attracted investments from top-tier venture capital firms, including Aeri Capital, BioMedInvest, Life Sciences Partners, the venture capital arm of Novo Nordisk A/S and OrbiMed.

In 2009, we formed AbCheck, our 100% owned, independently run antibody screening platform company, located in the Czech Republic. AbCheck is devoted to the generation and optimization of fully human antibodies. Its technologies include a combined phage and yeast display antibody library and a proprietary algorithm to optimize affinity, stability and manufacturing efficiency. AbCheck also uses a super human library as well as their newly developed mass humanization technology to discover and optimize high-quality human antibodies. In addition to providing candidates for Affimed projects, AbCheck is recognized for its expertise in antibody discovery throughout

the United States and Europe and has been working with globally active pharmaceutical companies such as Eli Lilly, Daiichi Sankyo, Pierre Fabre and others.

## B. Business overview

### *Our Strategy*

Our goal is to engineer targeted immunotherapies, seeking to cure patients by harnessing the power of innate and adaptive immunity (NK- and T-cells). We are developing single and combination therapies to treat cancers and other life-threatening diseases. For this, we have developed an entirely novel antibody platform that delivers two different types of next-generation antibodies, bispecific TandAbs and Trispecific Abs. Based on the unique properties and mechanism of action of these products and supported by the preclinical and clinical data we have generated to date, we believe that our product candidates, alone or in combination, may ultimately improve clinical outcomes in cancer patients and could eventually become a key element of modern targeted oncology care. Key elements of our strategy to achieve this goal are to:

- § ***Rapidly Advance the Development of our Clinical Stage Product Candidates, including Combinations with Other Immunotherapies.*** Our product development strategy initially targets relapsed or refractory cancer patients who have limited therapeutic alternatives, which we believe will enable us to utilize an expedited regulatory approval process. In the second quarter of 2015, a phase 2a proof of concept trial of AFM13 as a monotherapy was initiated by the German Hodgkin Study Group (GHSG) in HL patients that have received all standard therapies and have relapsed after or are refractory to Adcetris. We expect interim data in the second quarter of 2016 and primary endpoint data by the end of 2016. We are also supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University for which Columbia submitted an IND to the FDA that has since become effective. In addition, we have expanded our development strategy to combination therapies. We plan to initiate a phase 1b clinical trial to investigate AFM13 in combination with pembrolizumab (KEYTRUDA®) in HL patients that have relapsed after or are refractory to chemotherapy and Adcetris in the first half of 2016. For AFM11, we have begun a phase 1 dose escalation study designed to evaluate safety and tolerability and to potentially assess anti-tumor activity after four weeks of therapy in NHL patients. The phase 1 clinical trial is ongoing and recruiting with a modified dose regimen. The amended study protocol was approved by the applicable regulatory authorities in the third quarter of 2015. We expect to report first data from this phase 1 trial by the end of 2016.
- § ***Establish R&D and Commercialization Capabilities in Europe and in the United States*** We plan to retain rights for all of our product candidates, although in the future we may enter into additional collaborations that provide value for our shareholders. We intend to build a focused marketing and specialty sales team in Europe and in the United States to commercialize any of our product candidates that receive regulatory approval. We have established a U.S. presence in order to expand our access to the talent pool, maintain better control over our studies conducted in North America, maintain and expand our scientific and medical network, further increase our interaction with the FDA and maintain a close relationship to the financial community.
- § ***Use Our Technology Platforms and Intellectual Property Portfolio to Continue to Build our Cancer Immunotherapy Pipeline.*** We generate our product candidates from our proprietary antibody engineering technology platforms consisting of NK-cell TandAbs, T-cell TandAbs and Trispecific Abs. We plan to continue to leverage these technologies to develop new pipeline product candidates. We believe we can utilize our platforms to address additional targets that we may in-license in the future or identify internally. We intend to continue to innovate in our field and create additional layers of intellectual property in order to enhance the platform value and extend the life cycle of our products. We believe our strong intellectual property position can be used to support internal development as well as out-licensing and collaboration opportunities.
- § ***Maximize the Value of our Collaboration Arrangements with LLS, Amphivena/Janssen and Merck.*** We have a research agreement with LLS under which LLS has committed to co-fund up to \$4.4 million over two years for the phase 2a monotherapeutic development of AFM13. We believe that this collaboration will also allow us to expedite patient enrollment for future trials by leveraging the LLS's existing relationships

with key U.S. investigators. In 2013, we entered into a license and development agreement with Amphivena, which amended and restated a 2012 license agreement, to develop a CD33/CD3 TandAb candidate for AML in exchange for an interest in Amphivena and certain milestone payments. Amphivena has entered into an agreement with Janssen that gives Janssen the option to acquire Amphivena upon predetermined terms following acceptance by the FDA of an IND filing for the product candidate. Affimed has successfully reached its first three milestones, including the selection and acceptance of a development candidate. The third milestone was achieved in the first quarter of 2015. In January 2016, we entered into a clinical research collaboration with Merck & Co to investigate the combination of Merck's anti PD-1 therapy, KEYTRUDA<sup>®</sup> (pembrolizumab), with AFM13 for the treatment of patients with relapsed/refractory HL. We believe that these collaborations help to validate and more rapidly advance our discovery efforts, technology platforms and product candidates, and will enable us to leverage our platforms through additional high-value partnerships. As part of our business development strategy, we aim to enter into additional research collaborations in order to derive further value from our platforms and more fully exploit their potential.

- § **Intensify our Collaboration with Academia.** We have entered into collaborations with the German Hodgkin Study Group, Stanford University, the Mayo Clinic, the Columbia University, as well as with the German Cancer Research Center DKFZ. We finalized the establishment of a Scientific Advisory Board in the first half of 2015. We will continue to engage with key experts in our areas of interest with activities such as our Hodgkin Lymphoma KOL Day in January 2016.
- § **Utilize AbCheck to Generate and Optimize Antibodies.** We formed AbCheck in 2009 to leverage our antibody screening platform and partner with other biopharmaceutical companies in fee-for-service engagements. We use AbCheck's state-of-the-art phage and yeast display screening technologies as well as a proprietary batch humanization process and bioinformatics tools to identify and optimize antibodies that are highly specific for the targets we or our customers select, and that we engineer into TandAbs or Trispecific Abs. AbCheck's high-quality capabilities have been validated through multiple international collaborations including a strategic research partnership with Pierre Fabre.

### **Our Strengths**

We believe we are a leader in developing cancer immunotherapies due to several factors:

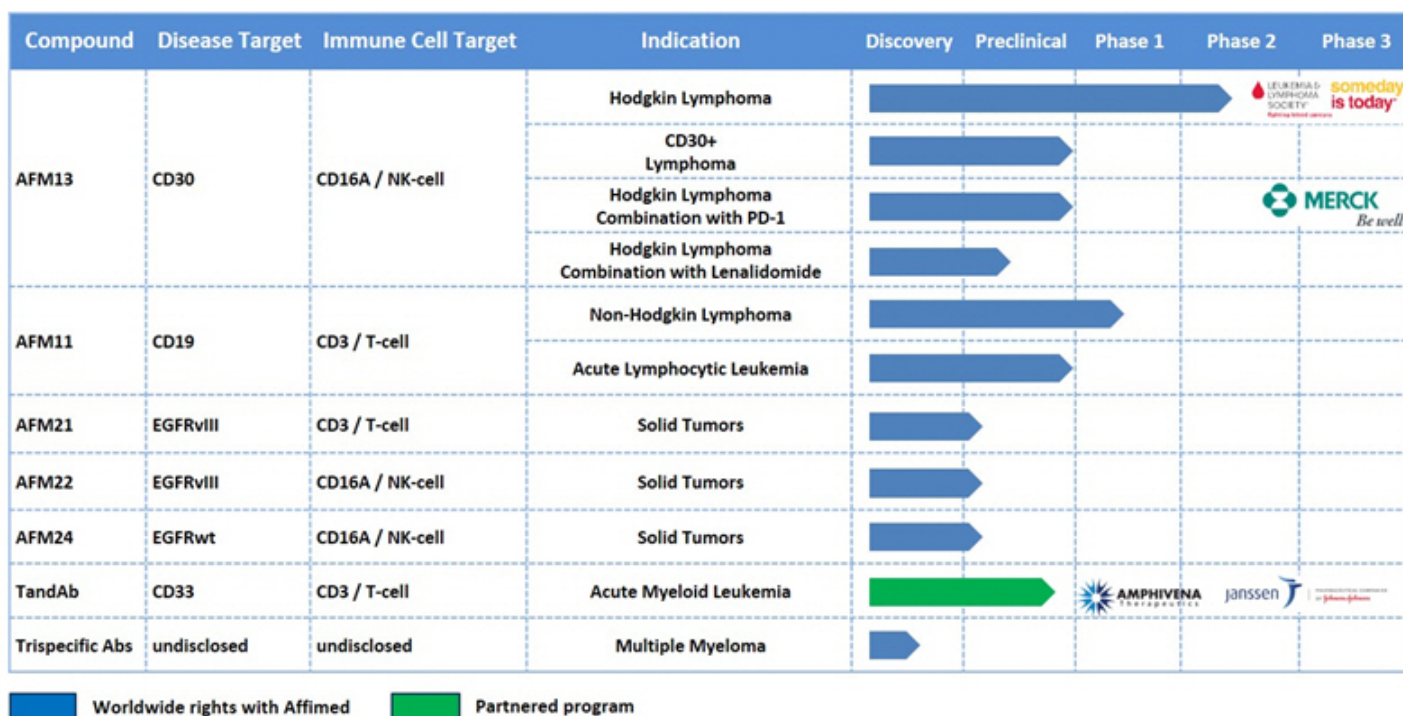
- § **Our Lead Product Candidate, AFM13, is a First-in-Class NK-Cell Mediated Cancer Immunotherapy.** AFM13 is a targeted immunotherapy that is currently in development for HL as a salvage therapy. To engage and activate NK-cells, we have engineered AFM13 with a unique binding specificity for CD16A. AFM13 binds to CD16A with approximately 1,000-fold higher affinity than native antibody molecules via the constant region. While native antibodies bind to CD16A and CD16B with similar affinity, AFM13 does not bind to CD16B at all. CD16B is expressed on the surface of neutrophils, which show very limited anti-tumor activity and exist in such large amounts that little would be left for NK-cell binding and tumor cell killing were AFM13 not to be so selective for only CD16A. We believe that AFM13 is the only antibody in development that can specifically engage CD16A+ cells, in particular NK-cells, with very high affinity. In the second quarter of 2015, a phase 2a proof of concept trial of AFM13 was initiated by the German Hodgkin Study Group (GHSG) in HL patients that have received all standard therapies and have relapsed after or are refractory to Adcetris. We expect interim data in the second quarter of 2016 and primary endpoint data by the end of 2016. The Leukemia and Lymphoma Society, or LLS, has agreed to co-fund this phase 2a HL study, a further indication of the promise this development candidate holds. We are also supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University for which Columbia submitted an IND to the FDA that has since become effective. In order to prepare for further clinical development, we have conducted preclinical studies investigating the combination of AFM13 with CPIs and checkpoint agonists, or CPAs (collaboration with Stanford University). Based on data from these studies, we plan to initiate a phase 1b clinical trial in collaboration with Merck to investigate AFM13 in combination with pembrolizumab (KEYTRUDA<sup>®</sup>) in HL patients that have relapsed after or are refractory to chemotherapy and Adcetris. We will be the sole sponsor of this trial, which we expect to initiate in the first half of 2016. A preclinical investigation of the combination of AFM13 with lenalidomide (collaboration with Mayo Clinic) is still ongoing.



- § **Growing Pipeline of Product Candidates Focused on Key Cancer Indications.** By leveraging our technology platform, we have built a growing pipeline of additional product candidates. Our second product candidate, AFM11, has demonstrated in preclinical studies highly specific and effective engagement of T-cells, inducing rapid and potent in vitro and in vivo tumor cell killing. AFM11 is expected to not require continuous infusion due to its half-life and has shown 100-fold higher affinity to CD3 compared to a reference molecule with the same sequence as Amgen's Blincyto (blinatumomab) and we believe it may have an efficacy advantage, especially in immunocompromised patients. We have begun a phase 1 dose ranging study of AFM11 designed to evaluate safety and tolerability and to potentially assess anti-tumor activity after four weeks of therapy in NHL patients. The phase 1 clinical trial is ongoing and recruiting with a modified dose regimen. The amended study protocol was approved by the applicable regulatory authorities in the third quarter of 2015. We believe that the new, less frequent dosing regimen provides a better opportunity to investigate potential benefits of AFM11 related to the molecular characteristics of TandAbs, i.e. the longer half-life and the higher affinity to T-cells compared to BiTEs. We expect to report first data from this phase 1 trial by the end of 2016. In addition, we are planning to investigate AFM11 in ALL patients and are preparing a phase 1 dose ranging study that is expected to begin recruitment in the first half of 2016. Our third product candidate, AFM21 (EGFRvIII / CD3), which is in preclinical development, addresses a target that to date has been elusive and that is abundant in certain solid tumors, including glioblastoma, prostate cancer and head and neck cancer, but not found on healthy tissue. In preclinical studies, AFM21 has demonstrated an ability to selectively kill EGFRvIII-carrying cells and not wild-type EGFR. In addition to the AFM21, which targets EGFRvIII on tumor cells and CD3 on T-cells, we further advanced an EGFRvIII/CD16A NK-cell TandAb, called AFM22. An additional CD16A NK-cell TandAb, called AFM24 targeting EGFR-wild type, a validated solid tumor target has been engineered and characterized preclinically. Based on data from ongoing experiments, we will decide which program to advance into IND-enabling studies.
- § **Retained Global Commercial Rights for our Five Candidates in our Product Pipeline.** Our five pipeline product candidates AFM13, AFM11, AFM21, AFM22 and AFM24 are unencumbered. We retain all options to derive value from our product candidates, including commercialization in all or select markets when and if they are approved. To maximize the value of our platform, we will continue to explore partnerships to support the development or commercialization of our programs in certain territories.
- § **Experienced Management Team with Strong Track Record in the Development and Commercialization of New Medicines.** Members of our management team have 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. Our Chief Executive Officer Adi Hoess and our Chief Medical Officer Jens-Peter Marschner were members of the teams that developed and commercialized Firazyr® and Erbitux®, respectively, while our Chief Operating Officer Jörg Windisch played a leading role in the development of Omnitrope®, Binocrit® and Zarzio®.
- § **Strong Technology Base and Solid Patent Portfolio in the Field of Targeted Immuno-Oncology.** We are a leader in the field of bi-and trispecific antibody therapeutics for the treatment of cancer. We have a patent portfolio that includes the tetravalent antibody platform itself. Further, we have a proprietary position in NK-cell engagement, specifically regarding binding domains directed at CD16A with no cross-reactivity to CD16B. We have more than a decade of experience in the discovery and development of such complex antibodies, and our molecular architecture allows for efficient and cost-effective manufacturing. In addition to supporting internal product development, we believe our strong intellectual property position can be used to support out-licensing and collaboration opportunities in the field of immuno-oncology.

**Our research and development pipeline**

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



Our lead candidate, AFM13, is a first-in-class NK-cell TandAb designed for the treatment of certain CD30-positive (CD30+) B- and T-cell malignancies, including Hodgkin lymphoma, or HL. AFM13 selectively binds with CD30, a clinically validated target in HL patients, and CD16A, an integral membrane glycoprotein receptor expressed on the surface of NK-cells, triggering a signal cascade that leads to the destruction of tumor cells that carry CD30. In contrast to conventional full-length antibodies, AFM13 does not bind to CD16B, which prevents binding to other cells, e.g. neutrophils.

We are initially developing AFM13 for HL in the salvage setting for patients who have relapsed after, or are refractory to, Adcetris (brentuximab vedotin), a CD30-targeted chemotherapy approved by the U.S. Food and Drug Administration, or FDA, in August 2011 as a salvage therapy for HL. Approximately half of the patients treated with Adcetris experience disease progression in less than half a year after initiation of therapy. In a recent phase 1 dose-escalation clinical trial, AFM13 was well-tolerated and demonstrated tumor shrinkage or slowing of tumor growth, with disease control shown in 16 of 26 patients eligible for efficacy evaluation. AFM13 also stopped tumor growth in patients who are refractory to Adcetris. Six out of seven patients who became refractory to Adcetris as the immediate prior therapy experienced stabilization of disease under AFM13 treatment according to Cheson’s criteria, standard criteria for assessing treatment response in lymphoma. We believe that based on its novel mode of action, AFM13 may be beneficial to patients who have relapsed or are refractory to treatment with Adcetris and may provide more durable clinical benefit.

In the second quarter of 2015, a phase 2a proof of concept trial of AFM13 was initiated by the German Hodgkin Study Group (GHSG) in HL patients that have received all standard therapies and have relapsed after or are refractory to Adcetris. We expect interim data in the second quarter of 2016 and primary endpoint data by the end of 2016. The Leukemia and Lymphoma Society, or LLS, has agreed to co-fund this phase 2a HL study, a further indication of the promise this development candidate holds. We are also supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University for which Columbia submitted an IND to the FDA that has since become effective.

In order to prepare for further clinical development, we are continuing to perform preclinical studies investigating the combination of AFM13 with CPIs and checkpoint agonists, or CPAs (collaboration with Stanford University), and lenalidomide (collaboration with Mayo Clinic). We believe that AFM13 and immunomodulators administered together could lead to greater tumor cell killing because these molecules may have a synergistic anti-tumor effect involving both NK-cells and T-cells. In preclinical animal studies of HL using both patient derived xenograft (PDX)

and immune cells from blood (PBMCs), the established tumor was treated with AFM13 and CPIs/CPAs (anti-PD-1, anti-CD137 and anti-CTLA4) both alone and in combination. While the single agent treatment showed a significant reduction in tumor growth for most molecules when compared to the control treatment group (irrelevant IgG), all combinations of AFM13 and CPI/CPA showed enhanced anti-tumor efficacy. We also analyzed the change in intra-tumoral lymphocyte population compared to IgG treatment. It was observed that in all AFM13-treated animals (as a single agent and in all combinations), the NK-cell population in the tumor increased. In addition, while there was no increase of T-cells in animals treated with only AFM13 or CPIs/CPAs, there was an increase of cytotoxic T-cells detected in animals treated with AFM13 in combination with a CPI/CPA. These results provide the rationale for the investigation of combinations with AFM13 in the clinical setting, initially focusing on PD-1. Preclinical data on the combination with CPIs/CPAs were presented at the American Society of Clinical Oncology (ASCO) annual meeting in 2015. Based on the preclinical data, we have entered into a collaboration with Merck and are planning to initiate a clinical phase 1b study investigating the combination of AFM13 with Merck's anti PD-1 antibody KEYTRUDA® (pembrolizumab) in patients with relapsed/refractory HL in the first half of 2016. The trial is designed to establish a dosing regimen for the combination therapy and assess its safety and efficacy.

Our second clinical stage candidate, AFM11, is a T-cell TandAb designed for the treatment of certain CD19+ B-cell malignancies, including non-Hodgkin Lymphoma, or NHL, Acute Lymphocytic Leukemia, or ALL, and Chronic Lymphocytic Leukemia, or CLL. AFM11 binds selectively with CD19, a clinically validated target in B-cell malignancies. It also binds to CD3, a component of the T-cell receptor complex, triggering a signal cascade that leads to the destruction of tumor cells that carry CD19. Based on its molecular characteristics, in particular its molecular weight, we expect AFM11 will have a longer half-life than blinatumomab, a bispecific antibody also targeted against CD19 and CD3 developed by Amgen, and approved in the United States and Europe. This should allow administration through bolus intravenous infusion, rather than continuous infusion, which requires hospitalization or a portable pump over one or more cycles of four-weeks each with frequent reconstitution and refill of medication, as is necessary for blinatumomab. In preclinical studies, AFM11 compared to the blinatumomab reference compound also showed a 100-fold higher affinity to the CD3 receptor, resulting in up to 40-fold greater cytotoxic potency at low T-cell counts. We have begun a phase 1 dose ranging study of AFM11 designed to evaluate safety and tolerability and to potentially assess anti-tumor activity after four weeks of therapy in NHL patients. The phase 1 clinical trial is ongoing and recruiting with a modified dose regimen. The amended study protocol was approved by the applicable regulatory authorities in the third quarter of 2015. We believe that the new, less frequent dosing regimen provides a better opportunity to investigate potential benefits of AFM11 related to the molecular characteristics of TandAbs, i.e. the longer half-life compared to BiTEs and higher affinity to T-cells. We expect to report first data from this phase 1 trial by the end of 2016. In addition, we are planning to investigate AFM11 in ALL patients and are preparing a phase 1 dose ranging study that is expected to be initiated in the first half of 2016.

We further are targeting Epidermal Growth Factor Receptor variant III, or EGFRvIII, a receptor that appears to be highly specific for solid tumors and is prominent in a significant portion of patients with glioblastoma, hormone refractory prostate cancer and head and neck cancer. Through access to our proprietary antibody libraries, we isolated antibodies that bind to EGFRvIII but not to wild-type EGFR, which is also expressed on many healthy tissues. In this context we have developed 2 bispecific antibodies, AFM21, an EGFRvIII/CD3 T-cell engager, and AFM22, an EGFRvIII/CD16A NK-cell engager. In preclinical studies, AFM21 and AFM22 have demonstrated a highly selective kill of EGFRvIII- but not wild-type EGFR- carrying cells. We will further compare the preclinical efficacy of both TandAb molecules and thereafter decide which one to advance into IND-enabling studies, which we expect to commence in 2016, with a potential IND-filing estimated in 2017.

We are also developing AFM24, an NK-cell-engaging TandAb targeting EGFR-wild type, which represents another validated antigen expressed by a variety of solid tumors. Constitutive EGFR activation through amplification or dysregulation plays an important role in the pathophysiology of numerous solid cancers, such as colorectal cancer (CRC), non-small cell lung cancer (NSCLC) or squamous cell carcinomas of the head and neck (SCCHN). We expect to initiate IND-enabling studies in 2016, with a potential IND-filing estimated in 2017.

In our collaboration with Janssen/Amphivena, we are developing a CD33/CD3-specific T-cell TandAb to treat acute myeloid leukemia (AML). We currently expect to file an IND for the lead candidate in 2016.

In addition, we are developing Trispecific Abs for various undisclosed targets which are currently at a discovery stage to be developed for indications such as multiple myeloma (MM).

## 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 (a part of 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.
- § T-Cells: T-cells are part of the adaptive immune system and only target cells that present antigen on their surface. The immune system recognizes a particular antigen and produces cytotoxic T-cells that bind to cells that present that antigen. As a result, billions of different structural variants can be recognized by the adaptive immune system, but each individual T-cell can only bind and respond to a single structure or molecule.

Increased understanding of the fundamentals of cellular and molecular tumor immunology has identified many ways in 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 bi- and trispecific antibody platforms enable a direct interaction of NK- or T-cells with cancer cells on the level of single cells leading to apoptosis, or 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 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. Once cancer spreads to sites beyond the primary tumor, it may be incurable. 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 Centers for Disease Control and Prevention, cancer is the second leading cause of death in the United States. In the United States, 1.66 million new cases of cancer are expected to be diagnosed in 2014, and more than 580,000 deaths from cancer are expected to occur. The overall 5-year survival expectancy is currently approximately 66%. There are an estimated 13 million people currently suffering from cancer. According to a National Institute of Health analysis, medical costs associated with cancer reached \$125 billion in 2010 and are projected to increase another 27% by 2020, to at least \$158 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 development, 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 non-specific mechanisms, such as 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, or 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 are cloned from a single parent cell, that target specific biological molecules in the human body that play a role in rapid 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®, Rituxan®, Erbitux® and Avastin® as well as small molecules such as Nexavar® and Tarceva®), 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 increasing role among emerging cancer drug therapies. The intention is to harness the body's own immune system to fight tumor cells or in some cases reestablish or remove certain blockades or signaling cascades. There are different approaches: vaccinations, checkpoint modulators that target co-stimulatory signals of the immune system, T-cell and NK-cell engagers, for example, bispecific antibodies, or cellular therapies involving transforming a patient's own T-cells to express chimeric antigen receptors (CARs). Ipilimumab (Yervoy®), sipuleucel-T (Provenge®), and more recently nivolumab (Opdivo®), pembrolizumab (KEYTRUDA®), and blinatumomab (Blincyto) were the first cancer immunotherapies to enter the market. Our platforms of bi- and trispecific antibodies add further promise to the field of immuno-oncology.

## Our Technologies

We generate our pipeline of product candidates from three proprietary platform technologies based on our proprietary tetravalent antibody architecture characterized by four binding domains, creating bispecific NK-cell and T-cell TandAbs (binding to two different targets) and Trispecific Abs (binding to three different targets). These molecules bind to specific targets on a tumor cell and to NK-cells or T-cells and thereby direct the immune cell to eliminate the tumor cell.

### *TandAbs*

Our TandAbs are designed with two binding domains for immune cell targeting and two for tumor cell targeting and can be engineered to engage two different types of immune cells, either NK-cells or T-cells.

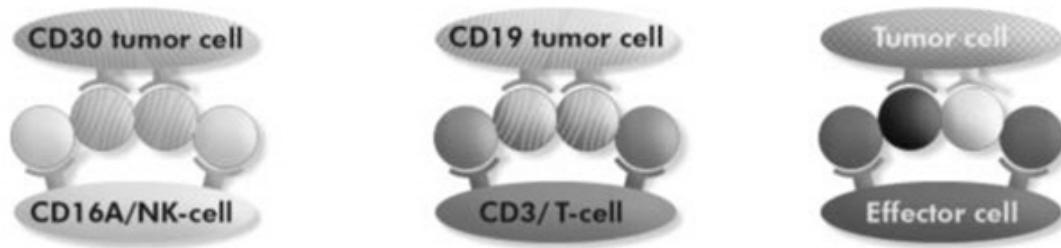
Specifically, they are designed to have the following properties:

- § 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.

### *Trispecific Antibodies (TriFlex)*

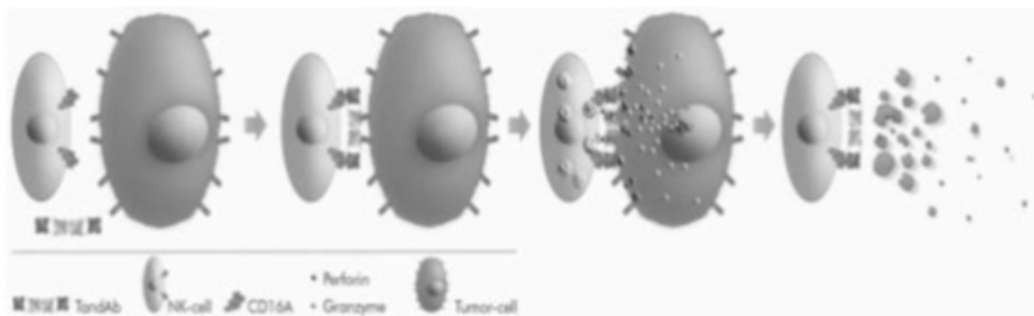
Like TandAbs, trispecific Abs also have two domains for immune cell targeting and two for tumor cell targeting, but their two tumor binding domains or effector cell binding domains can be distinct, each one designed to bind a different target on the tumor cell or effector cell, respectively (see illustration below). We are developing our Trispecific Abs as both NK-cell and T-cell engagers.

**Schematic representation of TandAbs (left and middle) and Trispecific Abs (right)**



**Schematic representation of the mode of action of an NK-cell TandAb: AFM13**

Our lead candidate NK-cell TandAb, AFM13, binds to CD30, a receptor found on the tumor cells of patients with HL and other CD30+ malignancies.



NK-cell with receptors CD16A and tumor cell with receptors CD30

NK-cell TandAb redirects the NK-cell to the tumor cell, forming an immunological synapse

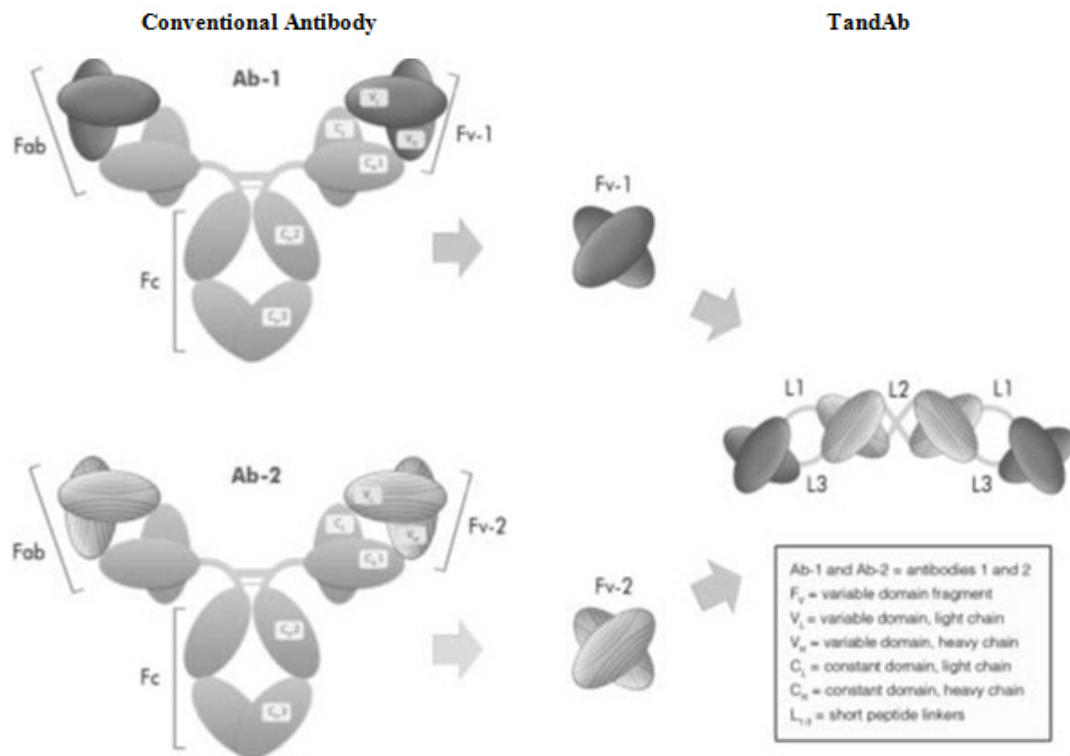
NK-cell releases perforin, creating pores in tumor cell membrane through which granzyme enters, triggering caspase

action trigger apoptosis of tumor cell. TandAb is released

***Comparison of conventional and TandAb antibodies***

Native, or naturally occurring, antibodies are Y-shaped proteins that are used by the immune system to target pathogens. Antibodies are comprised of two identical heavy chains and two identical light chains. The binding sites for target molecules are formed by the two variable domains of the heavy and light chains at the tips of the two arms, also referred to as Fv regions. The two Fv regions target the same antigen, and this bivalent binding to a receptor on the surface of a cell leads to an increase in binding strength. The Fc region can bind, recruit and activate immune system cells, including NK-cells, but not T-cells, to amplify the immune response to antigen bound by the Fv regions.

## Conventional Antibody TandAb



Our TandAbs consist of four FV domain fragments derived from two different parent antibodies. Two FV fragments bind specifically to a disease target, such as CD30 on a tumor cell, and the other two FV regions bind specifically to receptors of an immune cell, such as an NK-cell. In this way, our TandAbs are designed to bind with specificity to two different cells, a target cell and an effector cell. The FV domain fragments are connected by short peptide linkers. TandAbs are expressed from a single gene construct, and two chains of the resulting polypeptides assemble spontaneously in an intermolecular fashion to form the biologically active structure (a homodimer). Like the parent antibodies, a TandAb has two binding sites for each target: two domains bind to a receptor on an NK-cell or T-cell, and two bind to a receptor on tumor cells.

We have three proprietary platform technologies based on our proprietary tetravalent antibody architecture characterized by four binding domains:

- § NK-cell TandAbs—These bispecific antibodies are designed to bind with high affinity to a specific target on a tumor cell and to NK-cells and thereby direct the NK-cell to eliminate the tumor cell.
- § T-cell TandAbs—These bispecific antibodies are designed to bind with high affinity to a specific target on a tumor cell and to T-cells and thereby direct the T-cell to eliminate the tumor cell.
- § Trispecific Abs for dual targeting of tumor cells—These antibodies are designed to bind to two different targets on the tumor cell and to either T-cells or NK-cells and thereby direct the T-cell or NK-cell to eliminate the tumor cell.

We have established robust and efficient manufacturing processes for our TandAbs using a mammalian cell system, and they show good product stability. TandAbs are formulated as lyophilized powder and are reconstituted for infusion. The mean half-life (t<sub>1/2</sub>) of our lead TandAb AFM13 for dose cohorts = 1.5 mg/kg was 9-19 hours in

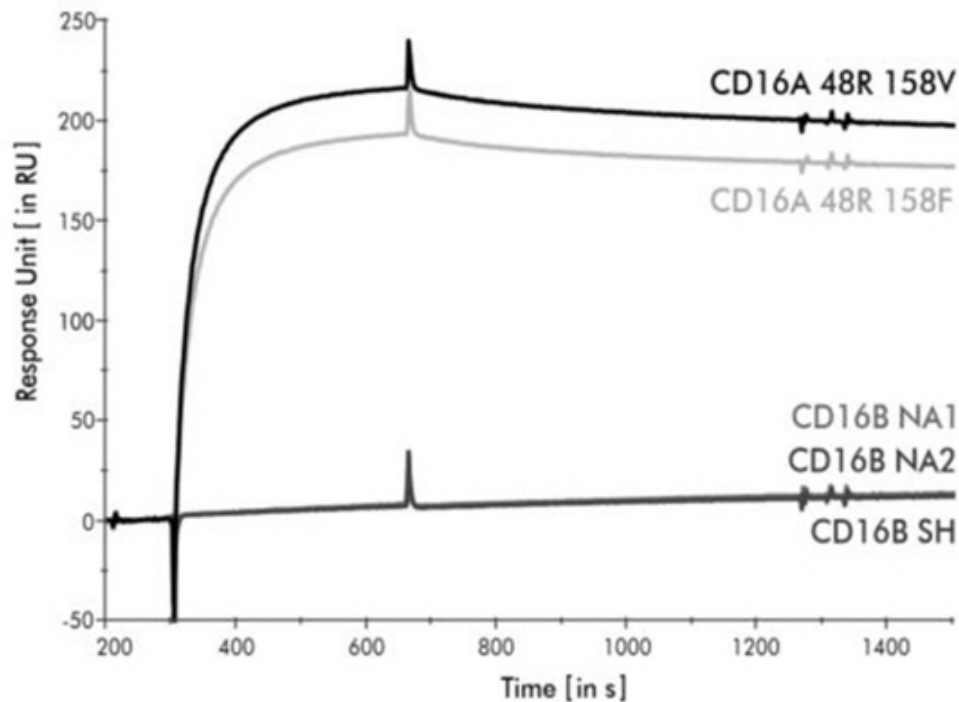
humans, and AFM13 is administered one to three times weekly by intravenous infusion over a one to four hour period.

### *NK-cell TandAbs*

NK-cells 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 NK-cells can bind to the Fc regions of native full-length antibodies to induce a cytotoxic effect, our NK-cell TandAbs are designed to enhance the activity of NK-cells in killing targeted tumor cells because they bind the Fc $\gamma$ RIIIA (CD16A) receptor on NK-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 NK-cells, but not neutrophils. Other therapeutic antibodies 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, represents an antibody sink by neutralizing such antibodies. To engage and activate NK-cells, we have generated a highly effective and specific human antibody that targets the CD16A receptor and does not cross-react with CD16B (see figure below).

**Binding of NK-cell TandAb to CD16A (high- and low affinity genetic variants (allotypes) 158V and 158F, respectively) and to CD16B (SH, NA1 and NA2 allotypes), the latter showing zero response (no binding)**



### *T-cell TandAbs*

CD4<sup>+</sup> or CD8<sup>+</sup> T-lymphocytes (T-cells) are primary effectors of adaptive immunity and launch an attack only once foreign or aberrant material is processed and small pieces thereof are presented to them. Our T-cell TandAbs are designed to tether a T-cell directly to a target on a tumor cell.



Our T-cell TandAbs bind with high affinity to the CD3 protein of the T-cell receptor and a target molecule on the tumor cell. Once our T-cell TandAbs recruit a T-cell to the tumor cell, the T-cell generates a strong activation signal that induces the release of cytotoxic proteins perforin and granzyme and results in the destruction of the cancer cell. Our T-cell TandAbs have demonstrated in preclinical studies target-dependent cytotoxicity at low picomolar concentrations, which we believe may allow us to achieve therapeutic doses in the microgram range. In the absence of a tumor cell, the binding to CD3 on the T-cells by the TandAbs is not sufficient to activate the T-cells.

Our T-cell lead candidate, AFM11, binds to CD3 and CD19, a B-cell receptor found on malignant cells that cause leukemia or lymphoma, including NHL. The high potency of AFM11 has also been measured at low T-cell counts, which may be of particular benefit to patients whose immune systems are compromised, for example by chemotherapy.

### ***Trispecific Antibodies (TriFlex)***

Our Trispecific antibody platform could pave the way for cancer products with a substantially widened therapeutic window. Through our proprietary tetravalent domain structure, we have the ability to generate antibodies that exhibit three different binding specificities. Such structures are normally challenging to make, but we have succeeded in generating such molecules and have found that they have all the features to be used as drug candidates, such as manufacturability and stability. Our initial work is aimed at targeting two different tumor targets, and with a third functionality, engaging T-cells or NK-cells to exert a cytotoxic effect. Targeting two tumor targets allows for greater selectivity for cancer cells, sparing healthy tissue and resulting in a wider therapeutic window by opening up the potential target space, or dose range within which the drug can be effective in eradicating cancer cells without causing unacceptable levels of side effects.

In January 2015, we were awarded a €2.4 million (\$3 million) grant program from the German Federal Ministry of Education and Research (BMBF). The grant, awarded under the BMBF's "KMU-innovative: Biotechnology – BioChance" program, will cover approximately 40% of funding for a research and development program to develop multi-specific antibodies for the treatment of multiple myeloma.

### **Our Target Markets**

#### ***HL and CD30-positive Malignancies***

HL is a type of lymphoma, which is a cancer originating from white blood cells called lymphocytes. CD30 is a cell membrane protein and tumor marker of different hematological malignancies of which HL is one of the more prevalent. There are approximately 9,000 new cases of HL in the United States every year and about 23,000 new cases in North America, the European Union and Japan.

Patients with newly diagnosed HL, depending on disease stage, are treated primarily with chemotherapy, usually 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, 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 is the first approved targeted therapy for HL patients that are relapsed/refractory to second line treatments. Adcetris 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 delivers a toxin (monomethyl auristatin E) to the cells that carry the CD30 receptor. The toxin is internalized by the tumor cell, which is then destroyed. In a phase 2 clinical trial, Adcetris treatment in relapsed/ refractory HL patients resulted in an overall response rate of 75% and a complete response rate of 34%. However, the median progression free survival after Adcetris is only 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).

Other CD30+ hematological malignancies include CD30+ T-cell lymphoma, or TCL, and CD30+ diffuse large B-cell lymphoma, or DLBCL (approximately 25% of DLBCL tumors express CD30), which together contribute

approximately 6,000-8,000 relapsed/refractory cancer cases per year in North America, the European Union and Japan.

### **NHL**

Among a large group of lymphomas, at least 80% belong to the NHL group. These cancers can originate from either malignant B-cells or T-cells, whereby B-cell derived NHL comprises the vast majority. NHL includes precursor B-cell tumors and 12 distinctly-defined mature B-cell tumors, among them DLBCL, follicular lymphoma, or FL, and mantle cell lymphoma, or MCL. The latter three subtypes are the focus of the clinical development of AFM11. The total annual incidence of all B-cell lymphoma subtypes in North America, the European Union and Japan is about 160,000 cases, of which 70,000 are in the United States. DLBCL alone represents about 46,000 new patients in North America, the European Union and Japan every year, and currently some 20,000 patients with DLBCL relapse from or become refractory to a series of standard treatments every year.

There is a high medical need for new treatment options in NHL, both in the first line setting and in the relapsed/refractory setting. Standard first line treatment of patients with NHL consists of the CHOP chemotherapy regimen. The regimen is usually combined with rituximab (an anti CD20 antibody). While this regimen results in a durable response for the majority of patients with aggressive disease, in patients with indolent, or slowly progressing, disease, the chemotherapy is less effective. The effect of treatments in relapsed/refractory NHL also depends on the type of disease. For instance, response rates achieved with new targeted therapies in follicular lymphoma (FL) or mantle cell lymphoma (MCL) are at least partially promising and ibrutinib (Impruvica®) was approved in the United States for MCL in 2013 based on phase 2 data showing a response rate of 66%. However, in diffuse large B-cell lymphoma (DLBCL), the largest group within NHL, data are less promising with response rates usually not exceeding 30%. Promising results for this patient population were seen with blinatumomab, a bispecific antibody with the same disease target and immune cell target as AFM11 (CD19/CD3). Preliminary data of a phase 2 study in relapsed/refractory NHL patients (n=21) showed a response rate of 42%. In addition, the first data from a phase 1 trial investigating a CD19-targeting CAR T-cell therapy in NHL showed a response rate of almost 80% (11 out of 14 patients).

### **Other CD19-positive Malignancies**

ALL, an aggressive type of leukemia characterized by an overproduction of lymphocytes in the bone marrow and the peripheral blood, is also primarily a B-cell disease and exhibits the CD19 receptor. According to the National Cancer Institute, in 2013 an estimated number of 6,000 ALL cases were newly diagnosed in the United States, more than half in children and adolescents. Treatment of patients with ALL usually consists of a regimen that includes vincristine, prednisone, and an anthracycline, with or without asparaginase, and results in a complete response rate of up to 80% in patients aged 1-18 years; for adults, complete response rates are considerably lower (about 30% for patients above 40 years of age). Recently, Blincyto (blinatumomab) has been approved in the United States and in the EU for Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). This product is a bifunctional molecule similar to AFM11 in its targeting features and has demonstrated a high response rate in the labelled adult population.

CLL, the most common type of leukemia in adults, exhibits the CD19 receptor as well. Malignant B-cells accumulate in the bone marrow and blood, where they crowd out healthy blood cells. In the United States about 16,000 new CLL cases are expected to be diagnosed and about 4,600 patients are expected to die from CLL annually.

There are many studies with investigational drugs ongoing in CD19+ malignancies, including CARs that are in early-stage development for several CD19+ malignancies. CARs are showing high response rates in early clinical studies.

### **EGFRvIII-positive Malignancies**

The EGFRvIII receptor appears to be highly specific for solid tumors and is prominent in glioblastoma, prostate and head and neck cancer. In the United States alone as many as 290,000 patients are newly diagnosed with these three diseases every year. The incidence of EGFvIII on solid tumors was investigated more than a decade ago, as shown in the table below.

**Incidence of EGFRvIII in Human Cancers**

TUMOR TYPE	POSITIVE/TOTAL	PERCENT POSITIVE	DETECTION TECHNIQUE
Glioblastoma	16/31	52%	Immunohistochemistry
	35/62	56%	Western blotting
	9/38	24%	RT-PCR
	8/12	67%	Immunohistochemistry
	7/12	58%	Western blotting
	5/12	42%	RT-PCR
	32/48	67%	cDNA sequencing
Breast	3/11	27%	Immunohistochemistry
	8/10	80%	RT-PCR
	21/27	78%	Western blotting
Ovary	24/32	75%	Western blotting
Non-small cell lung	5/32	16%	Immunohistochemistry
Prostate	38/38	100%	Immunohistochemistry

Source: Current Cancer Drug Targets 2(2), 2002.

In addition, EGFRvIII has been reported to be expressed in 40-80% of patients with head and neck cancer.

Current treatment options for solid tumors consist of a mix of surgery, chemotherapy, radiotherapy and targeted therapies. While historically chemotherapy or radiotherapy regimens were standard, now tumor specific biomarkers are considered more frequently in order to make a decision for optimal treatment of the individual patient. This opportunity was primarily driven by the development of innovative targeted therapies, in particular monoclonal antibodies and tyrosine kinase inhibitors. For example, prior to the treatment of non-small cell lung cancer the tumor is investigated for histology (adenocarcinoma vs. non-adenocarcinoma), K-RAS mutation, EGFR mutations, EML4-ALK mutation, BRAF expression, HER2 expression and others. A treatment decision is then made based on biomarkers in order to tailor treatment to the patient. In general, the treatment of solid tumors shows a clear trend towards an individualized treatment, also known as personalized medicine.

Monoclonal antibodies play an important role in the treatment of solid tumors. Herceptin, Erbitux and Avastin were first approved about 10 years ago and are now well established in the treatment of many different cancer entities. Erbitux is considered standard in the treatment of head and neck cancers, Herceptin for the treatment of breast cancer and Avastin has shown efficacy in patients with prostate, ovarian and lung cancer. Hormonal therapy plays a role in certain tumors the growth of which is triggered by hormones: breast cancer, ovarian cancer and prostate cancer. In addition, immunotherapies play an increasing role. The first immunotherapies became standard treatments about 5 years ago: the vaccine Provenge (Sipuleucel -T) in prostate cancer and the checkpoint inhibitor ipilimumab (anti CTLA-4 monoclonal antibody) in melanoma. The PD-1 checkpoint inhibitors nivolumab and pembrolizumab have been approved more recently for the treatment of melanoma, lung cancer. Many trials with cancer immunotherapies are ongoing. It is expected that immunotherapies will play an increasing role in the standard therapy of solid tumors. While considerable progress was made over the last decade in the treatment of solid tumors, there are some cancer types for which new treatments have not provided survival benefit for patients, one of which is glioblastoma. Overall, 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.

The focus for the development of our EGFRvIII TandAb will initially be on glioblastoma, prostate cancer and head and neck cancer, for which a considerable proportion of patients is EGFRvIII positive. According to the National Cancer Institute, 22,900 patients are newly diagnosed with brain tumors per year in the United States, and about 15% of them suffer from glioblastoma. These patients are usually treated with a combined approach of surgery, radiotherapy and chemotherapy with temozolomide playing a central role. Although many new treatment approaches have been investigated over the last decade, none showed a meaningful benefit for patients to date.

Prostate cancer is the second most frequently diagnosed cancer and the sixth leading cause of cancer death in males worldwide. There are about 233,000 new cases per year in the United States, according to the National Cancer Institute. Treatment depends on many factors and, depending on stage, surgery, radiotherapy, hormonal therapy (for

example, arbiraterone), chemotherapy (for example, docetaxel), targeted therapies (for example, Avastin) and/or immunotherapy (Provenge) are utilized.

About 52,000 new cases of head and neck cancer are diagnosed per year in the United States, according to the National Cancer Institute. Depending on stage, location and biomarkers of the disease, treatment consists of surgery, radiotherapy, chemotherapy (platinum based) and/or targeted therapy (for example, Erbitux or tyrosine kinase inhibitors).

## Our Product Candidates

Our development pipeline currently comprises five distinct product candidates for which we retain full commercial rights. Initially, we will 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 in the hope to expedite the time to market. 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 incremental commercial opportunities in the future.

### AFM13

#### Overview

AFM13 is a first-in-class NK-cell TandAb that we have engineered to bind with high affinity to CD30 expressing tumor cells while at the same time binding to CD16A surface proteins to activate NK-cells. AFM13 is intravenously administered in order to recruit NK-cells in peripheral blood and transport them to the tumor by binding to CD30. AFM13 has several advantageous characteristics:

- § By targeting CD16A, AFM13 binds with NK-cells but not neutrophils and is therefore more selective than full-length antibodies that bind to both CD16A and B.
- § 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 existing, known and relevant genetic variants of CD16A.

The clinical and preclinical data that we have accumulated to date suggest that AFM13 appears to be well differentiated from Adcetris, the first approved targeted therapy for HL patients that are relapsed/refractory to second line treatments. Although AFM13 employs the same disease target as Adcetris (CD30), the two compounds are fundamentally different in their mechanism of action: Adcetris is a targeted chemotherapy, while AFM13 is a targeted immunotherapy. Adcetris 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 an NK cell. Once the cells are in contact, the killing activity of the NK-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. 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 therapy, but ultimately into a longer clinical benefit. In addition, the off-target toxicity of Adcetris' 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' safety limitation, and because of the immunological approach, AFM13 may also address the short duration of response of Adcetris.

#### Clinical development of AFM13

We have conducted a phase 1 dose escalation clinical trial in patients with relapsed/refractory HL and a phase 2a clinical trial was initiated in the second quarter of 2015 by the German Hodgkin Study Group (GHSG) in HL patients that have received all standard therapies and have relapsed after or are refractory to Adcetris. We expect

interim data in the second quarter of 2016 and primary endpoint data by the end of 2016. AFM13 has been granted orphan drug status for the treatment of HL in the United States and the European Union.

We are also supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University for which Columbia submitted an IND to the FDA that has since become effective. Combination therapies play an important part of our development strategy. Currently preclinical studies are ongoing investigating the combinations of AFM13 with CPIs and lenalidomide. Based on our recently published preclinical data with CPIs at ASCO 2015 and at ASH 2015, we are planning to initiate a clinical phase 1b study investigating the combination of AFM13 with Merck's anti PD-1 antibody KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with relapsed/refractory HL in the first half of 2016. The trial is designed to establish a dosing regimen for the combination therapy and assess its safety and efficacy.

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

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

The trial 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.

Twenty-six of 28 patients 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%. The chart below shows for these 13 individual patients the best overall response measured as a percentage change in tumor volume from baseline (baseline = 0 at the y-axis) The volume is calculated as sum of perpendicular diameters (SPD) for selected lesions of the tumors based on CT-scans.

**AFM13-101 Best Overall Response in % Change in Tumor Volume from Baseline in 13 Patients who Received  $\geq 1.5$  mg/kg**

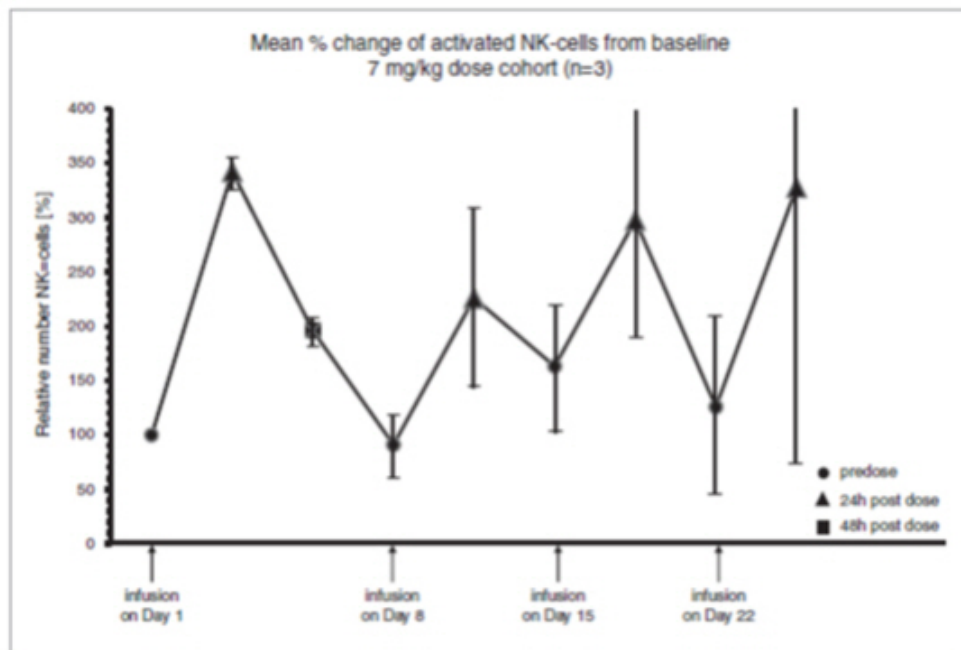


Six of seven patients refractory to Adcetris as their most recent treatment experienced stabilization of disease, or SD, following AFM13 treatment. One experienced progressive disease, or PD.

**AFM13-101 Data for Patients Refractory to Adcetris as Immediate Prior Therapy**

PATIENT	AFM13 DOSE (mg/kg)	# PRIOR TREATMENTS	MOST RECENT TREATMENT	TIME LAST	AFM BEST RESPONSE
				ADCETRIS-FIRST AFM13	
001-01	0.01 weekly	6	Adcetris, 5 cycles	1 month	SD
001-02	0.01 weekly	7	Adcetris, 8 cycles	1 month	SD
001-07	0.15 weekly	11	Adcetris, 7 cycles	3 months	SD
001-11	0.5 weekly	7	Adcetris, 5 cycles	3 months	SD
001-12	0.5 weekly	7	Adcetris, 9 cycles	1 month	SD
003-01	0.5 weekly	9	Adcetris, 4 cycles	1.5 months	SD
001-21	4.5 twice	8	Adcetris, 8 cycles	2.5 months	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  $\geq 1.5$  mg/kg was 9-19 hours. AFM13 treatment resulted in an increase of activated NK-cells, which are characterized by CD69 expression at 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, or sCD30, at the start of AFM13 treatment. sCD30 is shed by the tumor and measurable in peripheral blood. In 24 patients the level was decreased at the end of treatment. Patients treated in dosing cohorts  $\geq 1.5$  mg/kg all had a marked decrease of sCD30.

**AFM13-101: Relative number of activated (CD69+) NK-cells in patients receiving 7 mg/kg AFM13 (mean, n=3)**

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, in the phase 2a proof of concept study, the dose has to be  $\geq 1.5$  mg/kg; AFM13 has to be administered more frequently, at least for a certain time; the treatment duration has to be longer than four weeks; and a second cycle has to be mandatory in patients that showed benefit from AFM13 treatment in the first cycle, i.e. complete response, partial response or SD.

### ***Hodgkin Lymphoma***

#### *Phase 2a clinical trial*

In the second quarter of 2015, a phase 2a proof of concept trial of AFM13 was initiated by the German Hodgkin Study Group (GHS) in HL patients that have received all standard therapies and have relapsed after or are refractory to Adcetris. The primary endpoint is tumor response. We have designed the trial to demonstrate a response rate of greater than 30% for the selected dose as clinical experts consider a response rate of greater than 30% and a progression free survival time of greater than six months to be clinically meaningful for this patient population. Duration of response and progression free survival are secondary endpoints as we believe these time parameters, which indicate durability of efficacy, may differentiate AFM13 from Adcetris. We expect interim data in the second quarter of 2016 and primary endpoint data by the end of 2016. The Leukemia and Lymphoma Society, or LLS, has agreed to co-fund this phase 2a HL study, a further indication of the promise this development candidate holds.

If proof of concept is demonstrated in this phase 2a HL study, we plan to initiate a phase 2b study in relapsed/refractory HL. The exact design of this study would depend on the results of the phase 2a study and the end-of-phase-2 meetings with the FDA and European authorities. Because all input has to be considered carefully, we expect to have the first patient recruited in the registration study in 2017. We anticipate that the trial would run for approximately 2-3 years.

We believe that the phase 2b trial could support an application for registration in relapsed/refractory HL. This belief is based on the fact that AFM13 is being developed for an indication with high medical need because currently no other established treatment options are available for the targeted patient population. At the American Society of Hematology (ASH) meeting in December 2014, the first clinical data with two PD-1 checkpoint inhibitors, nivolumab and pembrolizumab, in refractory HL patients was published. The patient population was similar to the one included in the AFM13 phase 2a study. These early data showed high response rates, giving rise to breakthrough designation for nivolumab. We plan to refine our regulatory strategy as we generate additional clinical data for HL.

Competent authorities, including the FDA, have regulations in place that allow for an accelerated approval procedure in indications with high medical need. Recently, Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, summarized the intention of the FDA to help patients by streamlining drug approval procedures under certain circumstances. There are also numerous precedents for such approval strategies. For example, Adcetris received accelerated approval in 2011 based on data from an open label phase 2 study in 102 patients with relapsed/refractory HL. In addition, the FDA in 2014 approved Blincyto (blinatumomab) under breakthrough designation and accelerated review after only 2.5 months review time.

We discussed the development strategy of AFM13 with the FDA in a Scientific Advice Meeting held on February 19, 2014. The FDA stated that although it is possible to attain accelerated approval based on the strategy we outlined, more data from our clinical development program are needed to assess whether an accelerated approval procedure is reasonable. Once we are in possession of those data after the conclusion of our phase 2a trial, we intend to agree with the FDA on the precise requirements for approval in the context of an end-of-phase 2 meeting.

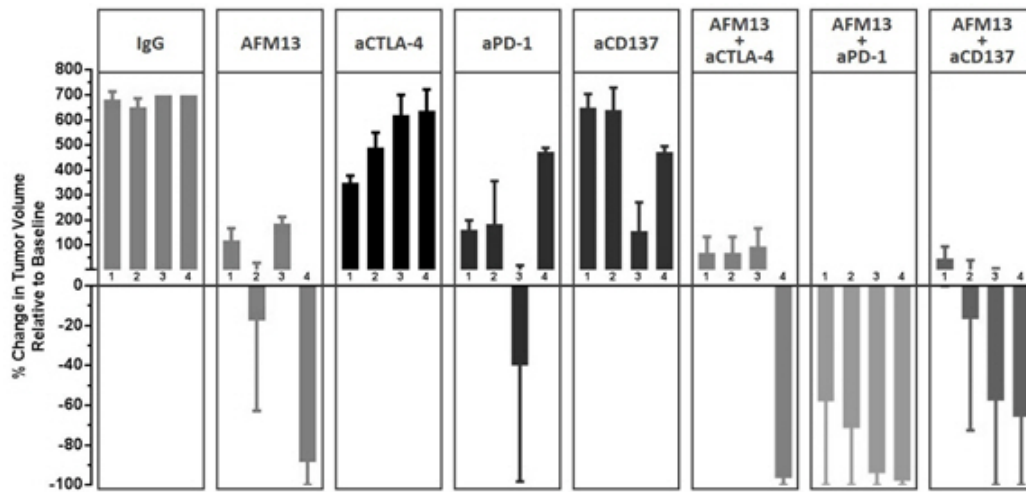
#### *Subsequent development plan for AFM13*

We are initially developing AFM13 for patients with relapsed/refractory HL, and we believe that AFM13 could have a broader application because it targets CD30, which is present on many cancer indications with a high unmet medical need.

We are also supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University for which Columbia submitted an IND to the FDA that has since become effective. In patients with lymphomas that are accessible through the skin, this study will be designed to allow for serial biopsies and therefore to interrogate the NK-cell biology and tumor cell killing within the tumor microenvironment when tumor tissue is exposed to AFM13. Such biopsies will also be useful to assess initial "pseudoprogression", that is the initial swelling of the tumor due to immune cell infiltration rather than tumor progression.

Based on its safety profile, AFM13 is suitable not only for monotherapy, but also as combination therapy. We are continuing to perform preclinical studies investigating the combination of AFM13 with CPIs and checkpoint agonists, or CPAs (collaboration with Stanford University), and lenalidomide (collaboration with Mayo Clinic). We believe that AFM13 and immunomodulators administered together could lead to greater tumor cell killing because these molecules may have a synergistic anti-tumor effect involving both NK-cells and T-cells. In preclinical animal studies of HL using both patient derived xenograft (PDX) and immune cells from blood (PBMCs), the established tumor was treated with AFM13 and CPIs/CPAs (anti-PD-1, anti-CD137 and anti-CTLA4) both alone and in combination. While the single agent treatment showed a significant reduction in tumor growth for most molecules when compared to the control treatment group (irrelevant IgG), all combinations of AFM13 and CPI/CPA showed enhanced anti-tumor efficacy [see graph]. We also analyzed the change in intra-tumoral lymphocyte population compared to IgG treatment. It was observed that in all AFM13-treated animals (as a single agent and in all combinations), the NK-cell population in the tumor increased. In addition, while there was no increase of T-cells in animals treated with only AFM13 or CPIs/CPAs, there was an increase of cytotoxic T-cells detected in animals treated with AFM13 in combination with a CPI/CPA. These results provide the rationale for the investigation of combinations with AFM13 in the clinical setting, initially focusing on PD-1. Final data on the combination with CPIs/CPAs were presented at the American Society of Clinical Oncology (ASCO) annual meeting in 2015. Based on the preclinical data, we are planning to initiate a clinical phase 1b study investigating the combination of AFM13 with Merck's anti PD-1 antibody KEYTRUDA<sup>®</sup> in patients with relapsed/refractory HL in the first half of 2016.





Another combination partner of interest is lenalidomide. Lenalidomide is approved for the treatment of multiple myeloma and is known to modulate the patient's immune system, e.g. by activation of NK-cells. In collaboration with an academic site preclinical experiments investigating the combination of lenalidomide with AFM13 are currently in preparation.

## AFM11

### Overview

AFM11 is a T-cell TandAb that we have engineered to bind with high affinity to both the CD19 receptor on certain tumor cells and CD3, a component of the T-cell receptor complex. CD19 is expressed on multiple B-cell malignancies, including various forms of NHL, ALL and CLL.

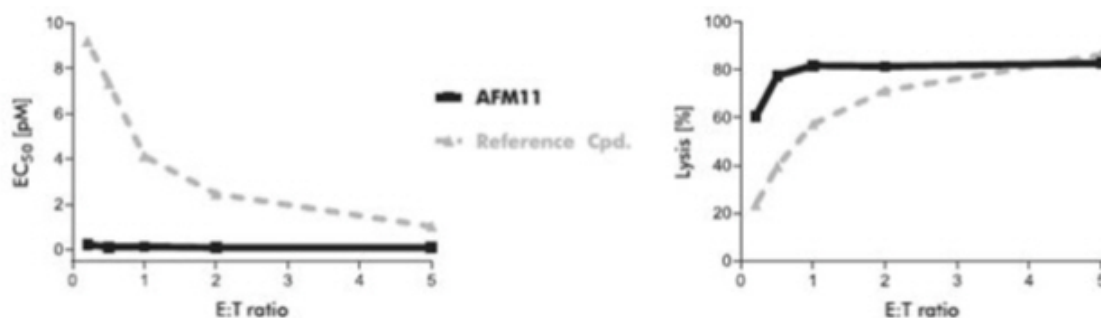
AFM11 has three advantageous characteristics:

- § To activate CD3 on the T-cell, AFM11 needs to bind to both targets. Thus, if there is a lack of CD19+ cells, no T-cell activation can be expected.
- § AFM11 has a molecular weight of 104 kDa. As shown for AFM13, which has a similar molecular weight, we believe AFM11 should have a half-life that allows for administration through intravenous infusion over one to four hours rather than continuous infusion (as needed for blinatumomab, which has a molecular weight of 55 kDa).
- § AFM11 is characterized by a high affinity to CD3, resulting in greater cytotoxic potency, especially at low T-cell counts. We believe that this may be important in immunocompromised patients.

The most promising clinical data for patients with relapsed/refractory B-cell malignancies is with Blincyto (blinatumomab), a bispecific antibody with the same disease target and immune cell target as AFM11 (CD19/CD3). Blincyto has meanwhile been approved for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The response rates observed with this molecule in clinical trials with patients with ALL are higher than those obtained with other experimental and approved treatments used currently in the salvage setting. Moreover, in ALL trials the complete responses were all molecular responses, that is CD19+ cells were completely ablated such that none were detectable with the most sensitive techniques available. Molecular response means absence of minimal residual disease, which is a predictor of long-term outcome, and hence this therapy may translate into extended progression-free survival and also overall survival.

The preclinical data that we have accumulated to date suggest that AFM11 appears to be well differentiated from blinatumomab. AFM11 has a molecular mass of 104kD, which should allow intravenous administration over one to four hours rather than continuous infusion, which is necessary for blinatumomab and requires initial hospitalization for monitoring followed by an at-home portable pump over a period of up to eight weeks. In preclinical studies comparing AFM11 to a reference molecule made with the same sequence as blinatumomab, AFM11 showed a 100-fold higher affinity to the CD3 receptor, resulting in greater cytotoxic potency. Unlike the reference compound for blinatumomab, for which cytotoxic potency decreases at lower effector cell to tumor cell ratios, AFM11's cytotoxic potency remains constant. Specifically, when tumor cells are 5x the number of T-cells (effector cell to tumor cell or E:T = 0.2), AFM11's potency is 40-fold higher than that of blinatumomab (figure below, left). In another experiment, AFM11 led to more complete tumor cell lysis (death) at low T-cell counts when compared to a blinatumomab reference compound (figure below, right). These findings may be of clinical importance because patients that have been treated with chemotherapy suffer from lymphopenia with a significant reduction in absolute T-cell numbers. These findings could theoretically also be of significance in tumor masses, which are poorly vascularized and to which T-cells have limited access.

**Cytotoxic potency (effective concentration (EC) for 50% cell lysis) of AFM11 in comparison to a reference compound with the same sequence as blinatumomab at various effector cell (T-cell) to tumor cell ratios. Left: cytotoxicity (stronger, if lower EC<sub>50</sub>); right: % cell lysis at 10 pM antibody concentration.**



### Clinical Development of AFM11

#### AFM11-101 phase 1 dose escalation clinical trial

In May 2014 we initiated a phase 1 clinical trial to assess the safety of AFM11 originally in patients with relapsed/ refractory CD19+ NHL and ALL. AFM11 is being administered using doses from 0.0003 up to 2.5 µg/kg per infusion. Patients with several subtypes of NHL will be included as long as they have received at least one rituximab-based chemotherapy regimen. In the third quarter of 2015 the study was amended and recruitment is ongoing investigating a modified dosing regimen in NHL. We believe that the new, less frequent dosing regimen provides a better opportunity to investigate potential benefits of AFM11 related to the molecular characteristics of TandAbs, i.e. the longer half-life compared to BITEs and the higher affinity to T-cells.

In addition, patients with NHL and ALL are now being investigated in two separate studies using different dosing regimens. The phase I study in ALL is expected to be initiated in the first half 2016.

The objectives of the studies are to determine the safety and tolerability of increasing doses of a single cycle of AFM11 monotherapy; to determine the maximum tolerated dose or optimal biological dose; to assess the PK of AFM11 in plasma; to assess the biological activity of AFM11; to assess PD markers in blood; to assess the anti-tumor activity of AFM11; and to recommend the dose for phase 2a studies in NHL and ALL patients, respectively.

The duration of the trials and number of patients treated will vary depending on the number of dose escalations. After implementation of the major amendment we anticipate that first data in NHL patients are available by the end of 2016.

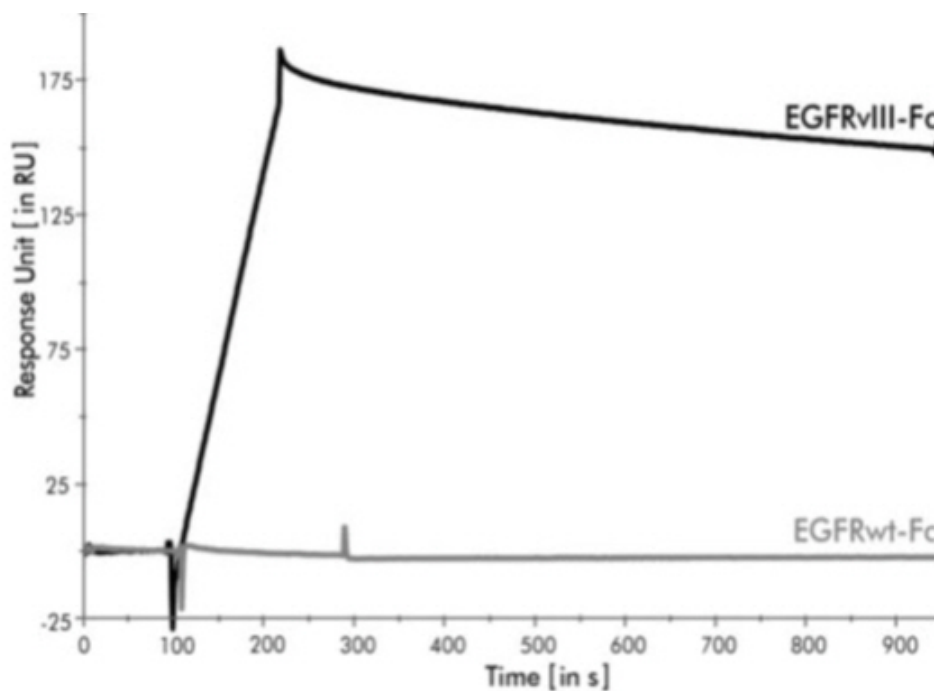
*Subsequent development plan for AFM11*

If our phase 1 clinical trial of AFM11 is successful, we may consider a number of options for the clinical development of AFM11. Our current clinical development plan focuses on NHL, in particular the subtypes DLBCL, FL and MCL. Upon conclusion of our phase 1 clinical trial, we will decide which, if any, NHL subtype we wish to develop AFM11 for.

**AFM21**

Our third TandAb program, AFM21, is in preclinical development. AFM21 selectively binds Epidermal Growth Factor Receptor variant III, or EGFRvIII, a receptor that appears to be highly specific for certain solid tumors and is prominent in a significant proportion of patients with glioblastoma, hormone refractory prostate cancers and head and neck cancers. AFM21 also binds CD3, directing T-cells to destroy tumor cells that carry EGFRvIII. Through our access to proprietary antibody libraries, we isolated an antibody that binds to EGFRvIII but not to wild-type EGFR, which is also expressed on many healthy tissues. In preclinical studies, AFM21 has demonstrated an ability to selectively kill EGFRvIII-carrying cells and not those expressing wild-type EGFR. In parallel to AFM21 we have also initiated development of an EGFRvIII/CD16A NK-cell TandAb, AFM22. We will compare the preclinical efficacy of both TandAb molecules and thereafter decide which one to advance into IND-enabling studies.

**Binding of AFM21 to EGFRvIII (upper curve, KD= 0.39 nM) and wild-type EGFR (EGFRwt, lower curve), the latter showing zero response (no binding)**



**AFM22**

AFM22 is an EGFRvIII/CD16A NK-cell TandAb, which is in preclinical development addresses the same target in some solid tumors as AFM21.

## AFM24

AFM24 is an additional CD16A NK-cell TandAb targeting a validated solid tumor target, EGFR-wild type. AFM24 has been engineered and characterized preclinically.

Based on pre-clinical data currently generated with AFM21, AFM22 and AFM24, we will decide which one to advance into IND-enabling studies.

## AbCheck

AbCheck is our wholly owned, independently operated proprietary antibody screening platform company. AbCheck combines three different technologies to supply high-quality antibodies to us as well as others on a fee-for-service basis. AbCheck offers phage display antibody libraries, yeast display and affinity maturation algorithm technologies. AbCheck is recognized for its expertise in antibody discovery throughout the United States and Europe and has been working with globally active pharmaceutical companies such as Eli Lilly, Daiichi Sankyo, Pierre Fabre and others.

### *Phage display antibody libraries*

AbCheck owns three phage display antibody libraries: a natural library, a synthetic library and a semisynthetic library, the latter designed to achieve reliable folding and high expression. These proprietary and validated libraries comprise a total of about 10<sup>10</sup> sequentially and structurally diverse antibodies and ensure the fast and reliable discovery of highly specific and highly affine human antibodies for virtually every possible target protein. AbCheck has conducted more than 30 successful antibody discovery projects, including antibodies against complex cell surface receptors.

### *Yeast display*

AbCheck uses yeast display to screen for enhanced expression levels and stability of antibodies and thereby select candidates that can be manufactured with high yield and are stable. The yeast system guarantees expression of the product candidate in customary cell culture systems. Furthermore, yeast display in combination with fluorescence activated cell sorting allows real-time monitoring and full control over the selection process. Screening in the final drug format, including full-length IgGs and novel antibody formats, ensures a fast and efficient lead discovery process.

### *Affinity maturation algorithm*

AbCheck has a proprietary algorithm, AbAccel, for incorporating the results of high-throughput antibody sequencing, structural analysis and therapeutic biochemistry to optimize antibodies with regard to affinity, immunogenicity, stability and expression levels.

### *SuperHuman Library*

AbCheck uses the SuperHuman library, an engineered library that aims to overcome current limitations of both fully synthetic and natural antibody libraries. The used design principles aim at providing a curated diversity that enriches drug-worthy frameworks in the resulting library and excludes frameworks that carry known biochemical liabilities.

### *Mass Humanization*

AbCheck has developed the mass humanization technology in partnership with Distributed Bio. It is an entirely new approach for multi-parameter engineering and optimization of monoclonal therapeutics. By analyzing the mutated repertoire of rabbits and humans, AbCheck was able to pre-compute and pre-encode the complete humanization landscape in a "mass humanization" technology, in which they humanize the *in vivo* immune response of a rabbit in a single experiment.

## Collaborations

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 additionally exploit their potential. Key terms of our current material collaborations are summarized below.

## **Amphivena**

### *Overview*

In 2013, we entered into a license and development agreement, which amended and restated a 2012 license agreement, with Amphivena Therapeutics, Inc., or Amphivena, based in San Francisco, CA, to develop a CD33xCD3 Tandab Antibody to be used in patients suffering from AML in exchange for an interest in Amphivena and certain milestone payments. Amphivena received funding from MPM Capital, Aeris Capital and us. Amphivena has also entered into an agreement with Janssen that gives Janssen the option to acquire Amphivena upon predetermined terms following acceptance by the FDA of an IND filing for the product candidate. Affimed has successfully reached its first three milestones, up to the generation and acceptance of a CD33xCD3 development candidate TandAb meeting certain target features. The third milestone was reached in the first quarter of 2015. Following the achievement of the third milestone of the Amphivena collaboration we were eligible to receive a milestone payment of €7.5 million payable in three installments. The first installment of €1.3 million was paid in the first quarter of 2015, and the second installment of €4.2 million was paid in October 2015.

In exchange for the technology license to Amphivena, we received shares of stock of Amphivena, and, in connection with an equity financing involving us and other third-party investors, we made cash investments in Amphivena in exchange for additional shares of stock and entered into certain related agreements governing our rights as a shareholder of Amphivena. As of December 31, 2015, those cash investments totaled \$ 900,000 (€732,619), and we owned approximately 21% of the outstanding equity of Amphivena on a fully diluted basis.

Amphivena has separately entered into a warrant agreement with Janssen Biotech Inc. that gives Janssen the option to acquire Amphivena following IND acceptance by the FDA of such product candidate, upon predetermined terms, in exchange for payments under the warrant. Janssen is obligated to make payments to Amphivena under the warrant upon Amphivena's achievement of specified milestones under the license and development agreement described below. Amphivena must use commercially reasonable efforts to research and develop the product candidate and carry out the corresponding development program. Affimed has successfully reached its first three milestones, including the selection and acceptance of a development candidate meeting the pre-specified criteria. In the event Amphivena fails to conduct any material development activity for a specified period or other important events defined in the warrant agreement that would prevent Amphivena from continuing the development program, among other rights, Janssen has the option to purchase Amphivena and/or to exercise an exclusive license under certain intellectual property controlled by Amphivena. In this situation, Janssen must still make certain reduced milestone payments ranging from low single digits to the low teen millions. Such payments will be made to Amphivena if Janssen elects to purchase Amphivena, or to us if Janssen exercises the right to license that certain intellectual property, as discussed above. The warrant agreement may be terminated at any time by mutual consent of Amphivena and Janssen and automatically terminates upon Janssen's failure to exercise the warrant once the exercise option is triggered, or to make payments required under the agreement. Janssen also may unilaterally terminate the warrant agreement upon specified events causing safety concerns, if the equity investors do not meet their funding obligations to Amphivena, or at any time provided that all milestone payments have been paid (regardless of whether such payments have become due).

We will receive payments (i) for research and development services to be provided by us under a license and development agreement entered into with Amphivena (as discussed below) and (ii) as a shareholder of Amphivena in the low-to-mid teen millions, if Amphivena is acquired by Janssen pursuant to the terms of the warrant.

### *License and development agreement*

**Overview.** Pursuant to the July 2013 license and development agreement between Amphivena and us, we will perform certain services for Amphivena related to the development of a product candidate for hematological malignancies.

**Licenses.** Pursuant to the license and development agreement, we have granted Amphivena certain product and technology licenses, each of which includes the right to grant sublicenses to its affiliates or third parties through multiple tiers, subject to certain notice requirements, including the following:

- § an exclusive, worldwide, royalty-free license under the TandAb technology to research, develop, make, have made, use and commercialize any TandAb developed under the agreement;
- § a non-exclusive, worldwide, royalty-free license under other antibody-specific intellectual property we control to research, develop, make, have made, use and commercialize any TandAb developed under the agreement; and
- § an exclusive, worldwide, royalty-free license under certain antibody-specific intellectual property we control to research, develop, make, have made, use and import certain antibodies and portions thereof or products derived therefrom developed under the agreement.

In addition, we have assigned our right and interest to certain intellectual property specifically related to certain antibodies covered under the agreement to Amphivena, and Amphivena solely owns all right, title and interest in certain intellectual property that specifically relates to such antibodies.

We and Amphivena have granted exclusive, worldwide, royalty-free cross-licenses to each other's know-how that is disclosed while the Janssen warrant agreement is in effect and otherwise not covered by patent rights, for use in connection with the development plan and on certain occasions in which the development plan continues to be carried out surviving termination of the license and development agreement.

*Service fees.* In consideration for the research and development work to be performed prior to IND acceptance by the FDA, Amphivena will pay to us service fees totaling approximately €16 million (net of our share in funding Amphivena) payable according to the achievement of milestones and phase progressions as described under the license and development agreement. Through December 31, 2015, €14 million (net of our share in funding Amphivena) has been paid to us under the license and development agreement. In February 2014, we entered into a letter agreement further delineating the services we will perform for Amphivena.

*Exclusivity.* During the term of the license and development agreement, we and our affiliates are prohibited from researching, developing, manufacturing, using or commercializing any compound or product for the treatment of acute myeloid leukemia (AML), subject to certain limited exceptions relating to services performed by AbCheck for its customers. We and our affiliates, including AbCheck, are also subject to additional restrictions on researching, developing, manufacturing, using or commercializing antibodies developed under the agreement.

*Term and termination.* Unless earlier terminated pursuant to the terms of the agreement, the license and development agreement terminates upon the completion of all services to be performed by us under the license and development agreement or any other determination or declaration by Amphivena (in its discretion) that a specified phase under the license and development agreement has been successfully completed or IND acceptance has been achieved for a lead candidate. The license and development agreement may also be terminated upon specified technical failures, certain failures to continue the development program or by either party for the other party's material breach, subject to a specified cure period, or if the other party undergoes specified bankruptcy or insolvency-related events. Janssen has rights under the license and development agreement to prevent termination of the agreement in certain situations in accordance with its rights under the warrant agreement.

### ***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 (€4.0 million) over two years to support the project. We have 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, four of which have been met. As a result, we have already received \$3.3 million in funds from LLS. We must use the funding provided by LLS exclusively with the development program, and return any excess funding to LLS. We are solely responsible for and have control over all development work and are obligated to use commercially reasonable efforts, as defined in the research funding agreement, in our conduct of the development program to achieve the specified milestones. We also have retained exclusive commercialization and distribution rights to AFM13. The research funding agreement was amended in April 2014 to amend the projected milestone event dates and modify certain aspects of the agreement regarding the phase 2a study design.

*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.

## **License Agreements**

### ***DKFZ***

*Overview.* In June 2006, we amended a 2001 license agreement with Deutsches Krebsforschungszentrum, Heidelberg, or DKFZ. Under the agreement, as amended, we obtained a worldwide, royalty-bearing license under specified DKFZ patent rights to make, have made, use, sell and have sold licensed products and to practice licensed commercial services, which specifically excludes services that are paid for with government grant funding. We have developed our TandAb technology under the licensed patent rights. In connection with the agreement, as amended, we issued DKFZ 350 shares of our Series C preferred shares, which were subsequently converted into Series D preferred shares in the equivalent amount of €50,000 and made a €35,000 cash payment to DKFZ. We are also required to pay DKFZ a low single digit royalty on net sales, as defined in the agreement, of licensed products and services and a mid-single digit percentage of income we receive in connection with granting a third party a sublicense of our rights under the license agreement. If we grant a sublicense in connection with entering into a cross-licensing arrangement with one or more third parties, we are obligated to make a lump-sum payment of DM 70,000 (€35,790) to DKFZ following the execution of each such sublicense. We are obligated to make the above royalty payments to DKFZ during the term of the licensed patents and for the two years following the expiration of the licensed patents.

*Patent rights.* DKFZ retains the right to use the licensed patent rights for scientific purposes. We are obligated to inform DKFZ of improvements relating to or similar to the licensed patent rights, licensed products or licensed services and DKFZ has the right to use these improvements for scientific purposes. DKFZ retains responsibility for the prosecution and maintenance of the licensed patent rights, but we are obligated to reimburse DKFZ for costs and expenses incurred in connection with the prosecution, maintenance and defense of the licensed patent rights.

*Exclusivity.* DKFZ originally granted us an exclusive license to the licensed patent rights for an already-expired initial period. The validity of the exclusive license automatically renews for subsequent one year terms unless either party provides written notice of a modification at least three months prior to the expiration of the then-current one-year term. No such modification has been issued by either party to date, and the license is in force on an exclusive

basis with respect to the licensed patent rights that relate to our TandAb antibody platform including our key product candidates.

*Term and termination.* The license agreement will terminate with the expiration of the last to expire licensed patent unless terminated earlier. Either party may terminate the license agreement for the other party's material breach, subject to a cure period. DKFZ may terminate the license agreement if we fail to meet certain diligence milestones with respect to commercialization, subject to certain exceptions. DKFZ may terminate by providing a specified period of prior written notice if we undergo certain insolvency or bankruptcy-related events.

## **XOMA**

*Overview and research license granted to us.* In September 2006, we entered into a license agreement with Xoma Ireland Limited, or XOMA. Pursuant to the agreement, XOMA granted us a worldwide, fully paid-up, royalty-free, non-exclusive and non-transferable license to conduct research on immunoglobulins under certain patent rights and know-how owned or otherwise controlled by XOMA. We refer to this research-only license grant as the "research license." The research license grants us the right to identify, select, isolate, purify, characterize, study and/or test immunoglobulins using XOMA's antibody phage display technologies.

*Options to license granted to us.* XOMA also granted us options, exercisable on an immunoglobulin-by-immunoglobulin basis, to obtain certain additional manufacturing or commercialization rights, including an option to obtain a worldwide, non-exclusive, non-transferable license under the licensed XOMA patent rights and know-how to make or have made (in a prokaryote and without use of a dicistronic construct), use, sell, offer to sell, import and otherwise commercialize immunoglobulins discovered, isolated or optimized under the research license for the diagnosis, treatment, prevention or prophylaxis of any human condition or disease. Unless XOMA grants us such a license, we are prohibited from commercializing, licensing or developing any immunoglobulin discovered, isolated or optimized under the research license. XOMA is not required to grant us a license upon our exercise of the option, unless the other provisions of the license agreement are complied with, including the requirement that we provide XOMA a specified form of prior written notice detailing the immunoglobulin with respect to which we wish to obtain a license. In addition, XOMA is not required to grant us such a license if the relevant immunoglobulin is already the subject of an exclusive license granted by XOMA to a third party or if XOMA can provide evidence of a bona fide development program for any immunoglobulin that binds to the same target as the immunoglobulin that is the subject of our request for a license pursuant to the option. For each immunoglobulin for which we obtain such a commercialization license pursuant to our exercise of the option, we are obligated to make milestone payments upon the occurrence of certain clinical and regulatory events. For each immunoglobulin, if all milestone events under the commercialization license are achieved, the aggregate milestone payments could total \$350,000. In addition, we are obligated to pay XOMA a low single digit percentage royalty on net sales on a country-by-country and immunoglobulin-by-immunoglobulin basis, until the later of the expiration of the last-to-expire valid patent claim in the relevant country or the tenth anniversary of the first commercial sale of the corresponding product.

*Our obligations.* We are required to use commercially reasonable efforts until phase 3 clinical trials to exploit the licensed patent rights in order to maximize the potential payments to XOMA under the license agreement. Both the research license and the license to commercialize specific immunoglobulins, if granted, would also extend to certain of our third-party collaboration partners, subject to the satisfaction of specified requirements.

*License granted to XOMA.* Pursuant to the agreement, we granted XOMA, its third-party development partners and its qualifying third-party licensees and licensors, a fully paid-up, non-exclusive, royalty-free, worldwide license (or sublicense, as the case may be) under certain of our patent rights relating to antibody phage display and certain patents that we in-license pursuant to specified license agreements to engage in research and to discover, isolate, optimize, develop, offer to use, use, offer for sale, sell, make, have made, export and import immunoglobulins or any product containing or comprising an immunoglobulin. XOMA may grant sublicenses to the extent reasonably necessary for XOMA, its development partners, and its licensees to license, develop, commercialize or otherwise enjoy the benefit of an immunoglobulin or other composition of matter or article of manufacture discovered, isolated, characterized or optimized by XOMA.

*Term.* The licenses we receive from XOMA under the agreement will remain in effect until the later of (i) ten years from the first commercial sale of the last immunoglobulin to be launched pursuant to a commercialization license granted by XOMA following our option exercise, or (ii) the expiration of the last to expire of the licensed XOMA



patent rights. The licenses we grant to XOMA and any XOMA development partners or licensees remain in effect until the last of the licensed patent rights expire.

*Termination.* Either party may terminate the licenses granted to the other party pursuant to the agreement for the other party's uncured material breach or insolvency. XOMA may elect to terminate our license rights if we undergo a qualifying change in control or sell substantially all assets related to antibody discovery, subject to certain limited exceptions. Termination of the agreement does not alter the rights or licenses granted to XOMA, its third-party development partners, any XOMA licensee or any applicable third-party licensees and licensors with respect to immunoglobulins, compositions of matter and other articles of manufacturing existing as of the effective date of termination, which would continue to be licensed pursuant to the terms of the agreement until the expiration of the last to expire of the applicable patent rights. In addition, our obligation to make the milestone and royalty payments, if applicable, will survive termination of the agreement.

## **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 our AFM13 (CD30 NK-cell TandAb) patent portfolio, which includes three patent families. Our first patent family is issued and relates to the engineered antibody format, which is called TandAb, and the methods of making or using such bispecific, tetravalent domain antibodies. This patent family will expire in 2019. The patents are granted in several major markets, including Australia, Canada, Europe (Austria, Belgium, Denmark, France, Germany, Great Britain, Italy, the Netherlands, Spain, Sweden and Switzerland/Liechtenstein), Japan and the United States. The second patent family on AFM13 is granted for the use of the specific target combination for the treatment of cancer using a bispecific molecule. This patent family is granted in Europe (Austria, Belgium, France, Germany, Great Britain, Ireland, Italy, the Netherlands, Spain and Switzerland/Liechtenstein) and will expire in 2020. Our third patent family relates to the mode of action of AFM13, the recruitment of immune effector

cells via a specific receptor. These patents will expire in 2026. We filed a related PCT application which entered the national phases in Australia, Brazil, Canada, China, Europe, Japan, Russia, India and the United States. Any patents resulting from these patent applications, if issued, also will expire in 2026. Patents have been granted in Australia, India, Russia, Europe (France, Great Britain, Germany, Switzerland and Liechtenstein, Belgium, Netherlands, Italy, Spain, Austria, Denmark and Sweden) and claims have been allowed in the United States.

#### *AFM11*

We own and/or control our AFM11 patent portfolio. This portfolio includes one patent family granted in Australia, Canada, Europe, Japan and the United States and one patent family pending in Australia, Brazil, Canada, China, Europe, Japan, Mexico, Russia and the United States. As in the case of AFM13, our issued patents relate to the engineered antibody format, which is called TandAb, and on which the AFM11 compound is based upon. These patents will expire in 2019. The pending patent application family claims a new TandAb structure which was specifically used in AFM11 to increase its potency. If issued, such patents will expire in 2030.

#### *AFM21*

We own and/or control the patents which cover our EGFRvIII/CD3 compound. This includes one granted patent family which is, comparable to AFM11 and AFM13, the patents on the TandAb format issued in Australia, Austria, Belgium, Canada, Denmark, France, Germany, Great Britain, Italy, Japan, the Netherlands, Spain, Sweden, Switzerland/Liechtenstein and the United States. We filed a PCT application relating to specific EGFRvIII/CD3 compounds. If issued, patents resulting from this PCT application will expire in 2034.

#### *AFM22*

We own and/or control the patents which cover our EGFRvIII/CD16A compound. This includes one granted patent family which is, comparable to AFM11 and AFM13, the patents on the TandAb format issued in Australia, Austria, Belgium, Canada, Denmark, France, Germany, Great Britain, Italy, Japan, the Netherlands, Spain, Sweden, Switzerland/Liechtenstein and the United States. We filed a PCT application relating to specific EGFRvIII/CD3 compounds. If issued, patents resulting from this PCT application will expire in 2034. As for AFM13, another patent family relates to the mode of action, recruiting of immune effector cells via a specific receptor, and will expire in 2026. Patents have been granted in Australia, India, Russia, Europe (France, Great Britain, Germany, Switzerland and Liechtenstein, Belgium, Netherlands, Italy, Spain, Austria, Denmark and Sweden) and claims have been allowed in the United States.

#### *AFM24*

We own and/or control the patents which cover our EGFRwt/CD16A compound. This includes one granted patent family which is, comparable to AFM11 and AFM13, the patents on the TandAb format issued in Australia, Austria, Belgium, Canada, Denmark, France, Germany, Great Britain, Italy, Japan, the Netherlands, Spain, Sweden, Switzerland/Liechtenstein and the United States. We are planning to submit a patent application covering composition of matter and, if issued patents resulting from this application will expire in 2036. As for AFM13, another patent family relates to the mode of action, recruiting of immune effector cells via a specific receptor, and will expire in 2026. Patents have been granted in Australia, India, Russia, Europe (France, Great Britain, Germany, Switzerland and Liechtenstein, Belgium, Netherlands, Italy, Spain, Austria, Denmark and Sweden) and claims have been allowed in the United States.

#### *TandAb platform*

We fully control our TandAb platform patent portfolio. The patent family 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 TandAb antibodies cover general diagnostic and therapeutic use, in particular for viral, bacterial or tumoral diseases. These patents will expire in 2019 and are granted in Australia, Canada, Europe, Japan and the United States. Another pending patent application covers TandAbs that have a different TandAb 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 TandAb platform is the Flexibody format. This antibody format is covered by a patent family, fully owned by us, which is granted in

Europe and Japan. A U.S. application is still pending; these patents and applications (if issued), respectively, will have a term until 2022.

### *Trispecific Antibodies*

Our latest platform development efforts resulted in the successful generation of trispecific antibody formats, for which we submitted a European patent application in 2014.

### ***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 TandAb 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 the patented technologies. Please see “—License Agreements.”

### ***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 TandAb product candidates in mammalian cells (CHO 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 commercial manufacturers (CMOs) which we select according to experience, track record and cost. Before and during the cooperation with a CMO we conduct audits to assess compliance with the mutually agreed process descriptions and current Good Manufacturing Practice, or cGMP regulations. Our manufacturers themselves are controlled by their

in-house quality assurance functions and inspected by regulatory agencies, including European national agencies and the FDA.

The technology transfer generally includes the development of a production cell line, the establishment of master and working cell banks, the development and qualification of upstream and downstream processes, the development of the drug product process, the development of suitable analytical methods for test and release as well as stability testing. During the development of our drug candidates, we or our CMOs scale the manufacturing process to suitable size. Such scaling up takes typically several steps and may involve modification of the process, in which case a renewed qualification of the manufacturing process with the relevant authorities is required. From our CMOs we receive process development-derived material for preclinical testing and material meeting cGMP standards for clinical supplies.

We rely on and will continue to rely on our 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.

We have successfully scaled up the AFM13 process and manufacturing material to meet the clinical drug demands for our clinical trials. We are also working with several external companies to establish a manufacturing process for the commercial phase. For AFM11 we may need a larger scale process as well, depending on the dose and regimen that will be determined in our phase 1 study.

### **Commercialization**

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

Prior to receiving marketing approvals, we plan to build a focused sales and marketing organization in the United States 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. Outside the United States, we expect to enter into license, distribution or other marketing arrangements with third parties to commercialize any of our product candidates that obtain marketing approval.

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 sales force. 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 is a large number of companies developing or marketing treatments for cancer disorders, 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.

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 2015 for the treatment of HL at high risk of relapse or progression

following autologous hematopoietic stem cell transplantation as consolidation treatment. In the European Union, Adcetris is approved for the same indications. Adcetris is currently being investigated in different settings and in various combinations in HL. Recent data indicate high complete response rates when combined with ipilimumab or bendamustine in relapsed/refractory HL. If and when AFM13 were to be approved for patients refractory to Adcetris, we would not compete directly with Adcetris. However, as we develop AFM13 for earlier-line therapies, for example in combination with other therapies as a second- or even first-line treatment, we would compete with Adcetris, which is in development for such indications.

Recently, phase 1 clinical data with the anti PD-1 checkpoint inhibitors nivolumab and pembrolizumab in HL was published in the New England Journal of Medicine and at ASH, respectively. These early data indicate the potential of anti PD-1 antibodies to cause high response rates in the salvage setting of HL. The FDA has granted a breakthrough designation for nivolumab in relapsed/refractory HL. Phase 2 studies are reported to be ongoing with nivolumab and pembrolizumab (registrational intent). Since we are preparing a clinical study of AFM13 in combination with pembrolizumab in relapsed/refractory HL, we do not necessarily anticipate competing with anti PD-1 antibodies. If AFM13 were to be approved for HL, we would be in competition with these therapies, as well as any other therapies or combination regimens that comprise the standard of care that AFM13 could potentially displace. In addition, several agents have reached proof of concept clinical trials in HL, including, Afinitor® (Novartis AG), ferritarg (MABLIFE), lirilumab (Innate Pharma), panobinostat (Novartis) and lenalidomide (Celgene). As of this date, definitive proof of the efficacy and safety of any of the new investigational agents in relapsed/refractory HL has yet to be obtained, leaving a substantial unmet need in this area for AFM13 to fill.

With respect to competitors for AFM11, rituximab has been approved to treat certain types of NHL in both the United States and Europe and is generally combined with a chemotherapy regimen (typically CHOP or bendamustine). Imbruvica, a small molecule drug targeting malignant B-cells, was approved by the FDA in 2013 to treat the mantle cell variant of NHL (MCL). Another small molecule drug, Gilead Sciences' Zydelig, was approved by the FDA for the treatment of follicular lymphoma (FL), which is also a variant of NHL. Amgen develops cancer product candidates which work by targeting receptors both on immune cells and cancer cells, like our TandAbs. Amgen's Blincyto (blinatumomab), a product based on BiTE (bispecific T-cell engager) technology, is an antibody construct similar to AFM11 and was approved by FDA and EMA to treat patients with relapsed/refractory Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL). MacroGenics' MGD011, a CD19xCD3 DART entered phase I in B-NHL and ALL and is being developed in partnership with Janssen Biotech. Morphosys is developing an Fc-enhanced anti-CD19 monoclonal antibody (phase II). Regeneron is developing a bispecific CD20xCD3 antibody for the treatment of NHL, which is currently in phase I. In October 2015, the FDA granted breakthrough designation to Pfizer's CD22-targeting antibody-drug conjugate inotuzumab ozogamizine for the treatment of relapsed/refractory B-ALL. A second CD19-targeting antibody-drug conjugate is being developed by Seattle Genetics and has entered phase II in NHL. Juno Therapeutics, Novartis, Bellicum, Cellectis and Kite Pharma are developing a therapy using T-cells reengineered with chimeric antigen receptors (CARs) against CD19-positive B-cells. This therapeutic approach, which utilizes a patient's own T-cells after ex-vivo genetic modification, is currently being investigated in early stage clinical trials. Although limited data are available, CAR treatments seem to result in high response rates specifically in ALL.

We expect that our TandAb and trispecific antibody platforms will serve as the basis for future product candidates and collaborations with pharmaceutical companies. Other companies also have developed platform technologies that compete with us. For example, MacroGenics is developing its DART platform, which enables the targeting of multiple receptors or cells by using a single molecule with an antibody-like structure. Ablynx is also developing such a platform aimed at multi-receptor targeting, which to date has not reached clinical testing.

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 trial sites and patient registration for clinical trials, 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 side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA 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. 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 requirements in the United States remain to be resolved, although Europe has already created the regulatory framework to approve biosimilar products.

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 trials, 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, 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 Conference on Harmonization 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, but are only used as guidance for the FDA. Nevertheless, in many areas of drug regulation ICH has resulted in comparable requirements, for instance with respect to the Common Technical Document, or the CTD, which has become the core document 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, 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 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, expensive, and inherently uncertain. Biologics development in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND (which must become effective before clinical testing may commence) and adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought. Developing the data to satisfy FDA pre-market approval 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 trials 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 practices. 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 trial 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 trials 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 has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials 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 trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, 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 trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial 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 trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials 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 severe or life-threatening diseases, such

as cancer treatments, initial human testing may be conducted in the intended patient population. Phase 2 usually involves trials 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 evaluations, phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. These phase 3 clinical trials 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. Trials 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 trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design and trial results in FDA public databases. These requirements are subject to specific timelines and apply to most controlled clinical trials of FDA-regulated products.

After completion of the required clinical testing, a 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, or biologics which present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. 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 and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, 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, 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 approval for a biologic may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or 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 or use of a companion diagnostic with a biologic can materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the biologic's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

After a BLA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots 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, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection.

#### *Fast track*

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 fast track product may be effective. A Fast Track designation provides the opportunity for more frequent interactions with the FDA, and a fast track product could be eligible for priority review if supported by clinical data at the time of submission of the BLA.

We plan to apply for a Fast Track designation for AFM13 in patients with relapsed/refractory HL, both as a monotherapy and as a combination therapy. A submission is planned for the first half of 2016.

#### *Biosimilars*

The Patient Protection and Affordable Care Act, which we refer to as the Affordable Care Act, signed into law on March 23, 2010, 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 and interchangeable biosimilars. Biosimilars are biological products which are "highly similar" to a previously approved biologic product or "reference product" and for which there are no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency. For FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation which are still being worked out by the FDA. To date, no biosimilar or interchangeable biologic has been licensed under the BPCIA framework, although such approvals have occurred in Europe, and it is anticipated that the FDA will approve a biosimilar in the relatively near future.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. A biosimilar application may be filed four years after the approval of the reference biologic. Although the patents for the reference biologic may be challenged by the biosimilar applicant during that time period pursuant to the BPCIA statutory patent challenge framework, no biosimilar or interchangeable product will be licensed by the FDA until the end of the exclusivity period. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after first commercial marketing, (ii) 18 months after the initial application if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the

application has been approved if a lawsuit is ongoing within the 42-month period. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will in fact be readily substituted by pharmacies, which are governed by state pharmacy law.

#### *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 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, manufacture, packaging, labeling, storage and distribution procedures must continue to conform to current 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.

#### *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 European Medicines Agency, or 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 trial application or CTA for each trial in humans, which must be approved before the trial may begin;
- § performance of adequate and well-controlled clinical trials 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 labelling;
- § 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 trial 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 trial approval***

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical trials 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 trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial 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 EU regulators are vital to make sure all relevant input and guidelines/regulations are taken into account in the overall program. We have established an ongoing dialogue with the PEI, the national competent authority in Germany regulating, among others, antibody products.

- § *Informal interactions:* We have had several informal discussions by phone with the PEI.
- § *Formal CHMP scientific advice:* We have not yet had a formal scientific advice meeting with the Committee for Medicinal Products for Human Use or CHMP, but plan to do so in time to discuss the further clinical development of AFM13.
- § *Formal national feedback:* We have had several scientific advice meetings with the PEI on AFM13 and AFM11. We also received written scientific advice from the PEI on special questions of the non-clinical development of AFM13 and AFM11. In the most recent scientific advice meeting the planned phase 2 study with AFM13 was reviewed and guidance was received which has been incorporated in our clinical development plan.
- § *Business pipeline meetings:* We have not yet sought business pipeline meetings.
- § *Paediatric investigation plans:* We are planning to submit a paediatric investigation plan to the EMA for AFM13 within the next year.

*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 trials, 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 paediatric studies are necessary and describes them in a PIP. This requirement for paediatric 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 paediatric 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 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 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. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is 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.

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)(i) 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;
- (a)(ii) 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
- (b) 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.

#### *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 after only ten (or eleven) years have lapsed.

As indicated, additional regulatory data protection 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 trials, 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 Therapeutics 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 and 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) under a revolving 24-month lease period, with a 12-month termination period. The lease could expire in 2019 if notice to terminate is provided by either party by February 2018. This facility serves as the corporate headquarters and central laboratory facility. We also lease office and laboratory space in the Czech Republic that is contracted until 2020 with a period of notice of three months. We believe that our existing facilities are adequate to meet current needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

**ITEM 4A. 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 under “Selected Financial Data” and 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 biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies. We develop our product candidates 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 natural killer cells, or NK-cells, and T-cells. Our proprietary, next-generation bispecific antibodies, called TandAbs because of their tandem antibody structure, are designed to direct and establish a bridge between either NK-cells or T-cells and cancer cells triggering a signal cascade that leads to the destruction of cancer cells. Due to their novel tetravalent architecture (which provides for four binding domains), our TandAbs bind to their targets with high affinity and have half-lives that allow regular, intravenous administration. 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.

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 milestone payments for collaborative research and development services. Through December 31, 2015, we have raised an aggregate of €171.2 million 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, 2015, we incurred a net loss of €20.2 million. As of December 31, 2015, we had an accumulated deficit of €120.2 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.



### ***Amphivena***

Pursuant to a July 2013 license and development agreement, which amended and restated a 2012 license agreement between us and Amphivena Therapeutics, Inc., or Amphivena, based in San Francisco, California, we licensed certain technology to Amphivena that enables Amphivena to develop an undisclosed product candidate for hematologic malignancies. In exchange for the technology license to Amphivena, we received shares of stock of Amphivena, and, in connection with an equity financing involving us and other third-party investors, we made cash investments in Amphivena in exchange for additional shares of stock and entered into certain related agreements governing our rights as a shareholder of Amphivena. As of December 31, 2015, those cash investments totaled \$0.9 million (€0.7 million), and we owned approximately 21% of the outstanding equity of Amphivena on a fully diluted basis.

Amphivena has separately entered into a warrant agreement with Janssen Biotech Inc. that gives Janssen the option to acquire Amphivena following IND acceptance by the FDA of such product candidate, upon predetermined terms, in exchange for payments under the warrant. If Amphivena is acquired by Janssen pursuant to the terms of the warrant, as a shareholder of Amphivena we would receive in the low-to-mid teen million U.S. dollars.

Pursuant to the July 2013 license and development agreement between Amphivena and us, we will perform certain services for Amphivena related to the development of a product candidate for hematological malignancies, and we have granted Amphivena certain product and technology licenses, each of which includes the right to grant sublicenses to its affiliates or third parties through multiple tiers, subject to certain notice requirements. In consideration for the research and development work to be performed prior to IND acceptance, Amphivena will pay to us service fees totaling approximately €16 million (net of our share in funding Amphivena) payable upon the achievement of milestones and phase progressions as described under the license and development agreement.

We recognized revenue of €4.4 million in the third quarter of 2013 upon achievement of the first milestone consisting of the earned milestone payment of €4.6 million less our share in funding Amphivena in 2013 of €0.2 million. A further payment of €2.0 million for research and development services was collected in the first quarter of 2014 and recognized as revenue upon achievement of the second milestone in the third quarter of 2014, net of our share in funding Amphivena of €0.2 million. In the third quarter of 2014 we received advance payments in total of €2.4 million for research and development services prior to achievement of the third milestone and deferred such amount as of December 31, 2014 until the milestone was achieved. In the first quarter of 2015, we recognized revenue of €2.4 million for the achievement of the third milestone which had been received in cash in 2014 and deferred until the milestone was achieved. After the achievement of the third milestone, we continue to provide research and development services to Amphivena for nonrefundable advance payments of €7.5 million, payable in three installments (€1.3 million, €4.2 million and €2.0 million). The first two installments totalling €5.2 million (€5.5 million, net of Affimed's share of €0.3 million) were received in 2015. We recognized €2.4 million as revenue for these research and development services in 2015 and €2.8 million was deferred as of December 31, 2015.

We are paid in euros under the license and development agreement.

### ***The Leukemia & Lymphoma Society***

In August 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 (€4.0 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 (€4.0 million) total that LLS agreed to contribute was conditioned on the achievement of certain milestones in connection with the development of AFM13, four of which have been met as of December 31, 2015. We achieved milestones in January 2014 and April 2014 and recognized revenues of \$1.5 million (€1.1 million) in total for related research and development services in 2014. We received additional milestone payments and recognized revenues of \$1.8 million (€1.6 million) in the second and third quarters of 2015. We must use the funding provided by LLS exclusively with the development program.

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. Amounts paid to us under our agreement with LLS are paid in U.S. dollars.

## License Agreements

### *DKFZ*

In June 2006, we amended a 2001 license agreement with Deutsches Krebsforschungszentrum, Heidelberg, or DKFZ. Under the agreement, as amended, we obtained a worldwide, royalty-bearing license under specified DKFZ patent rights to make, have made, use, sell and have sold licensed products and to practice licensed commercial services, which specifically excludes services that are paid for with government grant funding. We have developed our TandAb technology under the licensed patent rights. In connection with the agreement, as amended, we issued DKFZ 350 shares of our Series C preferred shares, which were subsequently converted into Series D preferred shares in the equivalent amount of €50,000 and made a €35,000 cash payment to DKFZ. We are also required to pay DKFZ a low single digit royalty on net sales, as defined in the agreement, of licensed products and services and a mid-single digit percentage of income we receive in connection with granting a third party a sublicense of our rights under the license agreement. If we grant a sublicense in connection with entering into a cross-licensing arrangement with one or more third parties, we are obligated to make a lump-sum payment of DM 70,000 (€35,790) to DKFZ following the execution of each such sublicense. We are obligated to make the above royalty payments to DKFZ during the term of the licensed patents and for the two years following the expiration of the licensed patents.

### *XOMA*

In September 2006, we entered into a license agreement with Xoma Ireland Limited, or XOMA. Pursuant to the agreement, XOMA granted us a worldwide, fully paid-up, royalty-free, non-exclusive and non-transferable license to conduct research on immunoglobulins under certain patent rights and know-how owned or otherwise controlled by XOMA. We refer to this research-only license grant as the “research license.” XOMA also granted us options, exercisable on an immunoglobulin-by-immunoglobulin basis, to obtain certain additional manufacturing or commercialization rights, including an option to obtain a worldwide, non-exclusive, non-transferable license under the licensed XOMA patent rights and know-how to make or have made (in a prokaryote and without use of a dicistronic construct), use, sell, offer to sell, import and otherwise commercialize immunoglobulins discovered, isolated or optimized under the research license for the diagnosis, treatment, prevention or prophylaxis of any human condition or disease. Unless XOMA grants us such a license, we are prohibited from commercializing, licensing or developing any immunoglobulin discovered, isolated or optimized under the research license. XOMA is not required to grant us a license upon our exercise of the option, unless the other provisions of the license agreement are complied with. For each immunoglobulin for which we obtain such a commercialization license pursuant to our exercise of the option, we are obligated to make milestone payments upon the occurrence of certain clinical and regulatory events. For each immunoglobulin, if all milestone events under the commercialization license are achieved, the aggregate milestone payments could total \$350,000 (€321,484). In addition, we are obligated to pay XOMA a low single digit percentage royalty on net sales on a country-by-country and immunoglobulin-by-immunoglobulin basis, until the later of the expiration of the last-to-expire valid patent claim in the relevant country or the tenth anniversary of the first commercial sale of the corresponding product.

## Financial Operations Overview

### *Revenue*

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

*Collaboration revenue.* Collaboration revenue of €4.4 million for the year ended December 31, 2013 was from the achievement of the first milestone under the license and development agreement with Amphivena. Collaboration revenue of €2.9 million for the year ended December 31, 2014 was from the achievement of the second milestone under the license and development agreement with Amphivena (€1.8 million) and from the LLS collaboration (€1.1

million). Collaboration revenue of €6.3 million for the year ended December 31, 2015 was from the achievement of the third milestone under the license and development agreement with Amphivena (€2.4 million), from research and development services under the license and development agreement with Amphivena (€2.3 million) and from the LLS collaboration (€1.6 million).

*Service revenue.* Service revenue is primarily revenue from service contracts entered into by AbCheck, our wholly owned, independently operated antibody screening platform. We recognized €0.7 million, €0.5 million and €1.3 million of service revenue in 2013, 2014 and 2015, respectively. Service revenue of AbCheck is dependent from third party contracts as well as from the utilization of the Unit by Affimed. In case Affimed increases or decreases the use of AbCheck's service capabilities that has an impact on the 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 Amphivena, and is expected to continue to vary, from quarter to quarter and year to year, depending upon, among other things, the structure and timing of milestone events, the number of milestones achieved, the level of revenues earned for ongoing development efforts, revenue from service contracts entered into by AbCheck, any new collaboration arrangements we may enter into and the terms we are able to negotiate with our partners. We therefore believe that period-to-period comparisons should not be relied upon as indicative of our future revenues.

### **Other Income**

In addition, we have earned income through several grants and/or contracts with the German government, the European Union and other educational institutions on behalf of the German government, primarily with respect to research and development activities related to the use of the TandAb technology in various indication areas.

### **Research and Development Expenses**

Research and development expenses consist principally of:

- § salaries for research and development staff and related expenses, including management 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.

We expect that our total research and development expenses in 2016 will be in the range of €34 to €40 million. Our research and development expenses primarily relate to the following key programs:

- § *AFM13.* The phase 2a clinical trial of AFM13 in Hodgkin Lymphoma, or HL, is ongoing and recruiting. In addition we are supporting an investigator-sponsored phase 1b/2a clinical trial of AFM13 in patients with CD30+ lymphoma conducted by Columbia University and planning to initiate a phase 1b study investigating the combination of AFM13 with Merck's anti PD-1 antibody KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with relapsed/refractory HL in the first half of 2016. We anticipate that our research and development expense will increase substantially in connection with the preparation and commencement of these clinical trials. In addition we will incur substantial expenses for the production of AFM13 clinical trial material and the investigation of commercial scale production options.

- § *AFM11*. The phase 1 clinical trial of AFM11 in patients with non-Hodgkin Lymphoma, or NHL, is ongoing and recruiting with a modified dose regimen. Due to the protocol amendment, the trial may require more patients compared to the original protocol. We also are planning to investigate AFM11 in acute lymphocytic leukemia, or ALL and are preparing a phase 1 dose-finding study that is expected to begin recruitment in the first half of 2016. Therefore, we anticipate that our research and development expense for the AFM11 program will increase in 2016.
- § *Other development programs*. Our other research and development expenses relate to our preclinical studies of AFM21/AFM 22 and AFM 24, our Amphivena collaboration and early stage development / discovery activities. We have allocated a material amount of the proceeds to such discovery activities. The expenses mainly consist of salaries and manufacturing costs for pre-clinical and clinical study material.
- § *Infrastructure costs*. 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 facility costs for further laboratory space and IP related expenses may increase over time.

Since January 1, 2012, we have cumulatively spent €54.7 million on research and development. In the years ended December 31, 2013, 2014 and 2015, we spent €14.4 million, €9.6 million and €22.0 million on research and development; €0.9 million, €4.2 million and €10.0 million on AFM13; and €6.5 million, €1.2 million and €0.8 million on AFM11. 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 the clinical development of AFM13 and AFM11 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, AFM11 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 U.S. Food and Drug Administration, or 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;

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- § 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 2016 will increase compared to the expenses in 2015 by roughly 25%, and will continue to increase in the future as our business expands. These public company-related increases will likely include costs of additional personnel, additional legal fees, accounting and audit fees, managing directors' and supervisory directors' liability insurance premiums and costs related to investor relations. In addition, we may grant share-based compensation awards to key management personnel and other employees.

## Results of Operations

The numbers below have been derived from our audited consolidated financial statements for the years ended December 31, 2013, 2014 and 2015. The discussion below should be read along with these financial statements, and it is qualified in its entirety by reference to them.

### Comparison of the years ended December 31, 2014 and 2015

	<b>Year ended December 31,</b>	
	<b>2014</b>	<b>2015</b>
	<b>(in € thousand)</b>	
<b>Total Revenue:</b>	<b>3,382</b>	<b>7,562</b>
Other income—net	381	651
Research and development expenses	(9,595)	(22,008)
General and administrative expenses	(2,346)	(7,548)
<b>Operating income/(loss)</b>	<b>(8,178)</b>	<b>(21,343)</b>
<b>Finance income—net</b>	<b>7,753</b>	<b>1,104</b>
Income/(Loss) before tax	(425)	(20,239)
Income taxes	166	0
<b>Income/(loss) for the period</b>	<b>(259)</b>	<b>(20,239)</b>
<b>Total comprehensive income/(loss)</b>	<b>(259)</b>	<b>(20,239)</b>
<b>Earnings/(loss) per common share in € per share</b>	<b>(0.01)</b>	<b>(0.71)</b>

#### Revenue

Revenue increased 124% from €3.4 million in the year ended December 31, 2014 to €7.6 million for the year ended December 31, 2015, mainly due to higher revenues from the Amphivena collaboration and higher service revenues at AbCheck in 2015.

Research and development expenses

R&D Expenses by Project	Year ended December 31,		Change %
	2014	2015	
	(in € thousand)		
Project			
AFM13	4,176	10,004	140%
AFM11	1,249	800	(36%)
Other projects and infrastructure costs	5,650	10,593	87%
Share-based payment expense/(credit)	(1,480)	611	—
<b>Total</b>	<b>9,595</b>	<b>22,008</b>	<b>129%</b>

Research and development expenses increased 129% from €9.6 million in the year ended December 31, 2014 to €22.0 million in the year ended December 31, 2015, mainly due to higher expenses for AFM13, other projects and infrastructure. For the year 2016, we anticipate significantly higher research and development expenses particularly from the expected start of additional clinical trials with AFM13 (phase 1b/2a trial of AFM13 in patients with CD30+ lymphoma and phase 1b combination trial of AFM13 with Merck's anti PD-1 antibody KEYTRUDA<sup>®</sup> in patients with relapsed/refractory HL), an additional clinical trial with AFM11 (phase 1 dose ranging study with AFM11 in ALL patients), production of clinical trial material and preclinical research activities. The variances in project related expenses between the year ended December 31, 2014 and the corresponding period in 2015 are mainly due to the following projects:

- § *AFM13*. In the year ended December 31, 2015, we incurred higher expenses due to the beginning of the phase 2a clinical trial and the manufacturing of clinical trial material for this study and for the additional studies expected to start in 2016.
- § *AFM11*. In the year ended December 31, 2015, clinical expenses were lower than in the year ended December 31, 2014 primarily due to higher expenses associated with the production of the clinical study material and the preparation of the phase 1 clinical study of AFM11 in 2014, whereas in 2015 we incurred expenses for the ongoing phase 1 study as well as expenses in relation to the trial protocol amendment.
- § *Other projects and infrastructure costs*. In the year ended December 31, 2015, expenses increased significantly primarily due to higher expenses associated with our internal R&D activities in 2015. Other projects comprise expenses incurred in relation to the AFM21 program and our discovery/early stage development activities. 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.

General and administrative expenses

General and administrative expenses increased 222% from €2.3 million in the year ended December 31, 2014 to €7.5 million in the year ended December 31, 2015. In 2014, general and administrative expenses were largely affected by a credit to the share-based payment expense of €3.4 million resulting from a re-measurement gain at consummation of the initial public offering (see Notes 2 and 19 to our financial statements as of December 31, 2015).

Finance income / (costs)-net

We recognized finance income net for the year ended December 31, 2015 of €1.1 million. The income reflects the net gains from foreign exchange differences less interest expense for borrowings under the Perceptive Credit Facility.

Finance income decreased in the year ended December 31, 2015 as compared to the year ended December 31, 2014. The year ended December 31, 2014 was primarily affected by the gain from the exchange of preferred shares of Affimed Therapeutics AG into common shares of Affimed N.V. and the decrease in the fair value of the derivative

conversion feature embedded in the convertible loan totaling €10.9 million. These preferred shares and convertible loan were no longer outstanding in 2015.

#### Income tax expense

During the year ended December 31, 2015, we did not incur any income tax expense.

#### Comparison of the years ended December 31, 2013 and 2014

	Year ended December 31,	
	2013	2014
	(in € thousand)	
<b>Total Revenue:</b>	<b>5,087</b>	<b>3,382</b>
Other income/(expenses)—net	610	381
Research and development expenses	(14,354)	(9,595)
General and administrative expenses	(7,046)	(2,346)
<b>Operating income/(loss)</b>	<b>(15,703)</b>	<b>(8,178)</b>
<b>Finance income/(costs)—net</b>	<b>(10,397)</b>	<b>7,753</b>
Income/(Loss) before tax	(26,100)	(425)
Income taxes	1	166
<b>Income/(loss) for the period</b>	<b>(26,099)</b>	<b>(259)</b>
<b>Total comprehensive income/(loss)</b>	<b>(26,009)</b>	<b>(259)</b>
<b>Earnings/(loss) per common share in € per share</b>	<b>(1.76)</b>	<b>(0.01)</b>

#### Revenue

Revenue decreased 34% from €5.1 million in the year ended December 31, 2013 to €3.4 million for the year ended December 31, 2014, mainly due to lower revenues from the Amphivena collaboration, partially offset by first time revenues from LLS in 2014.

#### Research and development expenses

R&D Expenses by Project	Year ended December 31,		Change %
	2013	2014	
	(in € thousand)		
Project			
AFM13	921	4,176	353%
AFM11	6,462	1,249	(81%)
Other projects and infrastructure costs	3,950	5,650	43%
Share-based payment expense/(credit)	3,021	(1,480)	—
<b>Total</b>	<b>14,354</b>	<b>9,595</b>	<b>(33%)</b>

Research and development expenses decreased 33% from €14.4 million in the year ended December 31, 2013 to €9.6 million in the year ended December 31, 2014, due to a credit to the share-based payment expense resulting from a re-measurement gain at consummation of the initial public offering (see Note 2 to our financial statements as of December 31, 2014). The variances in project related expenses between the year ended December 31, 2013 and the corresponding period in 2014 are mainly due to the following projects:

- § *AFM13*. In the year ended December 31, 2014 we incurred higher expenses due to the preparation for the phase 2a clinical trial and the manufacturing of clinical material for the phase 2a trial.
- § *AFM11*. In the year ended December 31, 2014, clinical expenses were significantly lower than in the year ended December 31, 2013. In 2013, expenses were higher due to the manufacturing of materials for clinical trials.
- § *Other projects and infrastructure costs*. In the year ended December 31, 2014 we continued to incur substantial costs related to the activities of the Amphivena collaboration. In contrast, in

2013, the collaboration had only been initiated at the beginning of the third quarter. 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.

#### *General and administrative expenses*

General and administrative expenses decreased 67% from €7.0 million in the year ended December 31, 2013 to €2.3 million in the year ended December 31, 2014, due to a credit to the share-based payment expense of €3.4 million resulting from a re-measurement gain at consummation of the initial public offering (see Notes 2 and 18 to our financial statements as of December 31, 2014).

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

We recognized finance income net for the year ended December 31, 2014 of €7.8 million. The income reflects the following transactions up to the consummation of the initial public offering and subsequently: the interest expense for preferred shares, the interest expense for the convertible loan, the interest expense for borrowings under the Perceptive Credit Facility, an extinguishment gain on the exchange of preferred shares of Affimed Therapeutics AG into common shares of Affimed N.V., the remeasurement gain resulting from changes in fair value and the extinguishment gain of the derivative conversion feature (see the table in Note 11 to our financial statements as of and for the year ended December 31, 2014).

Finance income increased in the year ended December 31, 2014 as compared to the year ended December 31, 2013 as a result of the transactions described above.

#### *Income tax expense*

During the year ended December 31, 2014, we recorded a tax income of €166,000 due to changes in deferred tax assets.

### **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.

Information about assumptions and estimation uncertainties that have a significant risk of resulting in a material adjustment within the next financial year are included in note 4 to our consolidated financial statements included elsewhere in this Annual Report and below:

#### ***Share-Based Payments***

We issue share-based payment awards under the terms of our ESOP 2014. We determine the compensation expense by estimating the fair value of a stock option as of the date of grant.

The fair value of stock options 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 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.



### **Revenue Recognition**

Elements of consideration in collaboration and license agreements are non-refundable up-front research funding payments, technology access fees and milestone payments. Generally, we have continuing performance obligations and therefore up-front payments are deferred and the related revenues recognized in the period of the expected performance. Technology access fees are generally deferred and recognized over the expected term of the research service agreement on a straight line basis.

We estimate that the achievement of a milestone reflects a stage of completion under the terms of the agreements and recognizes revenue when a milestone is achieved. If the research service is cancelled due to technical failure, the remaining deferred revenues from upfront payments are recognized.

### **Recent Accounting Pronouncements**

We refer to note 4 to our consolidated financial statements as of and for the year ended December 31, 2015 with regard to new standards and interpretations not yet adopted by us.

### **JOBS Act Exemptions**

On April 5, 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an emerging growth company, we are electing to take advantage of the following exemptions:

- § not providing an auditor attestation report on our system of internal controls over financial reporting;
- § not providing all of the compensation disclosure that may be required of non-emerging growth public companies under the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act;
- § not disclosing certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation; and
- § not complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis).

These exemptions will apply for a period of five years following the completion of our initial public offering (through 2019) or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier. We would cease to be an emerging growth company if we were to have more than \$1.0 billion in annual revenue or have more than \$700 million in market value of our common shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period.

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

Since inception, we have incurred significant operating losses. For the years ended December 31, 2013, 2014 and 2015, we incurred net losses of €26.1 million, €0.3 million and €20.2 million, respectively. To date, we have financed our operations primarily through public offerings of our common shares, private placements of equity securities and loans, grants and revenues from collaboration partners. As of December 31, 2015, we had cash and cash equivalents of €76.7 million.

Our cash and cash equivalents have been deposited primarily in savings and deposit accounts with original maturities of three months or less. Saving and deposit accounts generate a small amount of interest income. We expect to continue this investment philosophy but could consider to deposit our cash in savings and deposit accounts with slightly longer (6 months) maturities.

**Cash Flows***Comparison of the years ended December 31, 2014 and 2015*

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2014 and 2015:

	<b>Year ended December 31,</b>	
	<b>2014</b>	<b>2015</b>
	<b>(in € thousand)</b>	
Net cash used in operating activities	(10,547)	(18,535)
Net cash used for investing activities	(298)	(277)
Net cash generated from financing activities	44,889	53,498
Net changes to cash and cash equivalents	34,044	34,686
Cash and cash equivalents at the beginning of the year	4,151	39,725
Exchange-rate related changes of cash and cash equivalents	1,530	2,329
Cash and cash equivalents at the end of the year	39,725	76,740

The increase in net cash used in operating activities by 76% from €10.5 million in the year ended December 31, 2014 to €18.5 million in the year ended December 31, 2015 was mainly due to higher cash expenditure for research and development efforts and higher general and administrative cost.

Net cash used for investing activities remained unchanged with €0.3 million.

Net cash generated from financing activities increased from €44.9 million in the year ended December 31, 2014 to €53.5 million in the year ended December 31, 2015. The 2015 amount mainly includes the net proceeds from the public offering in May 2015 and the net proceeds received from the private placement in October 2015.

*Comparison of the years ended December 31, 2013 and 2014*

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2013 and 2014:

	<b>Year ended December 31,</b>	
	<b>2013</b>	<b>2014</b>
	<b>(in € thousand)</b>	
Net cash used in operating activities	(5,678)	(10,547)
Net cash used for investing activities	(157)	(298)
Net cash generated from financing activities	5,084	44,889
Net changes to cash and cash equivalents	(751)	34,044
Cash and cash equivalents at the beginning of the year	4,902	4,151
Exchange-rate related changes of cash and cash equivalents	0	1,530
Cash and cash equivalents at the end of the year	4,151	39,725

The increase in net cash used in operating activities by 84% from €5.7 million in the year ended December 31, 2013 to €10.5 million in the year ended December 31, 2014 was mainly due to the increase of cash effective expenses. While cash effective expenses in the year ended December 31, 2013 totaled €12.3 million (total expenses of €20.8 million less non cash effective expenses totaling €8.5 million), cash effective expenses in the year ended December 31, 2014 totaled €16.1 million (total expenses of €11.6 million plus non cash effective income totaling €4.5 million).

The increase in net cash used for investing activities from €0.2 million in the year ended December 31, 2013 to €0.3 million in the year ended December 31, 2014 was due to acquisition of laboratory equipment.

The increase in net cash generated from financing activities from €5.1 million in the year ended December 31, 2013 to €44.9 million in the year ended December 31, 2014 was mainly due to an increase in average cash and cash equivalents following the completion of our initial public offering, the Series E Financing (as defined herein) and the borrowing of funds under the Perceptive Credit Facility.

### ***Cash and Funding Sources***

Our cash and cash equivalents as of December 31, 2015 were €76.7 million. Funding sources generally comprise proceeds from the issuance of equity instruments, revenues from collaboration agreements and government grants.

On July 24, 2014, our subsidiary Affimed Therapeutics AG (now Affimed GmbH) entered into an agreement for a loan facility (the “Perceptive Credit Facility”) with an affiliate of Perceptive Advisors LLC. The Perceptive Credit Facility originally provided for aggregate funding of \$14.0 million, including \$5.5 million in initial funding and up to an additional \$8.5 million of capital available in subsequent tranches. In 2015, we agreed with Perceptive to cancel the option to draw the remaining available \$8.5 million.

The loans outstanding under the Perceptive Credit Facility accrue interest at an annual rate equal to an applicable margin of nine percent plus one-month LIBOR, with LIBOR deemed to equal 1% if LIBOR is less than 1% and is payable in monthly installments of interest only through April 2016 and then principal and interest thereafter in monthly installments through August 2018, with the outstanding balance to be repaid in full at the end of August 2018. Borrowings under the Perceptive Credit Facility are secured by a substantial portion of our tangible assets and intellectual property. Under the loan agreement governing the facility, we are subject to customary affirmative and negative covenants including limitations on additional indebtedness, limitations on liens, limitations on acquisitions and other restrictions related to our tangible assets and intellectual property. Additionally, covenants set forth under the facility will require us to maintain a minimum cash balance of \$2.0 million. We have also agreed to achieve certain development milestones for AFM11 and AFM13. We have entered into a discussion regarding the facility with Perceptive, including with respect to the development milestones.

Following the closing of our initial public offering, we issued to Perceptive 106,250 warrants at an exercise price of \$8.80 in accordance with the loan agreement governing the facility.

On September 17, 2014, we completed our initial public offering of common shares in which we sold an aggregate of 8,000,000 common shares at a price to the public of \$7.00 per share. The proceeds to us from the offering were approximately €43.2 million, before deducting the underwriting discounts, commissions and offering expenses.

In January 2015, we announced that we had been awarded a €2.4 million (\$3 million) grant from the German Federal Ministry of Education and Research (BMBF). The grant, awarded under the BMBF’s “KMU-innovative: Biotechnology–BioChance” program, will cover approximately 40% of expenses for a research and development program to develop multi-specific antibodies for the treatment of multiple myeloma. The grant payments are scheduled to be made periodically through the end of 2017.

On May 12, 2015, we announced the closing of our offering of 5,750,000 common shares at a public offering price of \$7.15 per common share. The total amount includes 750,000 common shares issued pursuant to the underwriters’ option to purchase additional shares which was exercised on May 7, 2015. After deducting the underwriting discounts and other offering expenses, the net proceeds of the public offering were €33.5 million (\$37.5 million).

On October 14, 2015, we sold 3.3 million shares to SGR Sagittarius Holding AG, an existing shareholder affiliated with Aeris Capital AG, in a private placement exempt from registration, resulting in net proceeds to us of €19.1 million (\$21.8 million).

### ***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 AFM13, AFM11, AFM21/AFM22 and AFM24. If we receive regulatory approval for AFM13, AFM11, AFM21/AFM22 or AFM24, 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 expect to incur additional 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.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until the first quarter of 2018. 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 collaborative, licensing, and other arrangements that we 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares. In this context we are also considering the restructuring of our existing debt financing with Perceptive or entering into new or additional debt financing agreements to address our funding needs, including to extend our cash reach.

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. Off-balance sheet arrangements**

As of the date of this Annual Report, we do not have any off-balance sheet arrangements other than operating leases as described under “Item 5. Operating and Financial Review and Prospects—F. Tabular disclosure of contractual obligations” below.

**F. Tabular disclosure of contractual obligations**

The table below sets forth our contractual obligations and commercial commitments as of December 31, 2015 that are expected to have an impact on liquidity and cash flow in future periods. In addition to license agreements with fixed payment obligations, we have entered into various collaboration and license agreements that may trigger milestone payments and royalty payments upon the achievement of certain milestones and net sales in the future. Because the achievement and timing of these milestones and net sales is not fixed or determinable, our commitments under these agreements have not been included in the table below.

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>Between 1 and 3 years</b>	<b>Between 3 and 5 years</b>	<b>More than 5 years</b>
	<b>(in € thousand)</b>				
Operating lease obligations	1,288	298	759	231	0
Fixed license payments	344	344	0	0	0
Perceptive Credit Facility	5,780	2,105	3,675	0	0
<b>Total</b>	<b>7,412</b>	<b>2,747</b>	<b>4,434</b>	<b>231</b>	<b>0</b>

*Operating lease obligations*

Operating lease obligations consist of payments pursuant to non-cancellable operating lease agreements relating to our lease of office space. The lease term of our premises in the Czech Republic is contracted until the year 2020 with a period of notice of three months. The lease period for the premises in Germany is extended automatically for 24 months if not terminated 12 months prior to the end of the lease period. The current lease period ends on February 28, 2019.

*Fixed license payments*

These payments relate to two license agreement for the use of certain technologies by our subsidiary AbCheck. AbCheck has the right to terminate these agreements yearly at the end of each year and at any time during the term of the agreement, respectively.

*Contingencies*

We have entered into various license agreements that contingently trigger on-off payments upon achievement of certain milestones and royalty payments in the future. Because the achievement and timing of these milestones and net sales is not fixed and determinable, our commitments under these agreements have not been included in the Contractual Obligations table above.

**G. Safe harbor**

See “Forward Looking 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 us 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 appointed by the general meeting of shareholders on January 21, 2016. Ulrich M. Grau was appointed by the general meeting of shareholders on June 9, 2015, and his term was effective as of July 1, 2015. Our other supervisory directors were appointed by the general meeting of shareholders on September 12, 2014, with effect from September 17, 2014. 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	64	2017
Bernhard R.M. Ehmer	61	2019
Ulrich M. Grau	67	2018
Berndt Modig	57	2017
Richard B. Stead	63	2016
Ferdinand Verdonck	73	2017

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 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 the board of directors of Cell Medica Ltd., Delenex AG and as a director of Humabs BioMed AG. Until the beginning of March 2015, he served as chairman of the supervisory council of SuppreMol GmbH. 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. He has been chairman of the board of management of Biotest AG since January 2015. 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 served as an advisor to our board from May 2013 until June 2015 and became a board member in July 2015. He has over 30 years of experience in the biotechnology and pharmaceutical industries including 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 whose development pipeline included Humira. The majority of his career was at Aventis Pharma, where he last held the position of senior VP of global late stage development. Lantus® 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.

**Berndt Modig, Director.** Mr. Modig has been a member of our supervisory board since 2014. He has served as Chief Financial Officer of Prosensa Holding N.V. from March 2010 through January 2015 when Prosensa was acquired by BioMarin Pharmaceutical Inc. Mr. Modig also serves as member of the board of directors and chairman of the audit committee of Auris Medical Holding AG and Axovant Sciences Ltd. Mr. Modig has more than 25 years of international experience in finance and operations, private equity and mergers and acquisitions. Before joining Prosensa, Mr. Modig was Chief Financial Officer at Jerini AG from October 2003 to November 2008, where he directed private financing rounds, its initial public offering in 2005 and its acquisition by Shire plc in 2008. Prior to Jerini, Mr. Modig served as Chief Financial Officer at Surplex AG from 2001 to 2003 and as Finance Director Europe of U.S.-based Hayward Industrial Products Inc. from 1999 to 2001. In previous positions, Mr. Modig was a partner in the Brussels-based private equity firm Agra Industria from 1994 to 1999 and a Senior Manager in the Financial Services Industry Group of Price Waterhouse LLP in New York from 1991 to 1994. Mr. Modig served as a director of Mobile Loyalty plc from 2012 to 2013. Mr. Modig has a bachelor's degree in business administration, economics and German from the University of Lund, Sweden and an M.B.A. degree from INSEAD, Fontainebleau, France and is a Certified Public Accountant.

**Richard B. Stead, Director.** Dr. Stead has been a member of our supervisory board since 2007. He has more than 25 years of experience in the biotechnology and pharmaceutical industries, designing and directing clinical trials, regulatory strategy and licensing activities. He is currently Founder and Principal of BioPharma Consulting Services, where he is involved in the development of a number of oncology products including different strategies

for cancer immunotherapy. Previously, he was Vice President, Clinical Research of Immunex Corporation, responsible for oncology and neurology product development. Dr. Stead has served in various positions in clinical development and played a key role in the FDA approval and commercialization of Amgen's first two products, Epogen and Neupogen. Dr. Stead graduated from the University of Wisconsin and earned an M.D. from Stanford University. He completed his internship and residency as well as a fellowship in Hematology at Harvard Medical School and the Brigham and Women's Hospital followed by post-doctoral research in the Laboratory of Molecular Biology at the National Cancer Institute. He also serves on the boards of Ascend Biopharmaceuticals Ltd. and the Seattle Repertory Theatre.

**Ferdinand Verdonck, Director.** Mr. Verdonck has been a member of our supervisory board since July 2014. He is chairman of the supervisory board of uniQure N.V. and is a director and a member of the Audit Committee of Virtus Funds and Laco Information Services. In recent years he was director of Groupe SNEF, director and member of the audit committee of J.P. Morgan European Investment Trust and director and chairman of the audit committee of two biotechnology companies in Belgium, Movetis and Galapagos. He has previously served as chairman of Banco Urquijo and of Nasdaq Europe and as a director of Dictaphone Corporation. From 1992 to 2003, he was the managing director of Almanij NV, a financial services company which has since merged with KBC, and his responsibilities included company strategy, financial control, supervision of executive management and corporate governance, including board participation in publicly-traded and privately-held companies in many countries. Mr. Verdonck holds a law degree from KU Leuven and degrees in economics from KU Leuven and the University of Chicago.

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

<b>Name</b>	<b>Age</b>	<b>Position</b>
Adi Hoess	54	Chief Executive Officer
Florian Fischer	48	Chief Financial Officer
Jens-Peter Marschner	53	Chief Medical Officer
Jörg Windisch	45	Chief Operating 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.

**Florian Fischer, Chief Financial Officer.** Dr. Fischer joined us in 2005 as Chief Financial Officer on a part-time basis, which has increased over time to a full time position since September 2014. Dr. Fischer is founder and Chief Executive Officer of MedVenture Partners, a Munich-based corporate finance and strategy advisory company focusing on the life sciences and health care industry. Dr. Fischer was the Chief Financial Officer of Activaero GmbH from 2002 until 2011 and has been involved with corporate development since 2011. He also served as the Chief Financial Officer of Vivendy Ltd. from 2008 until 2013 and as a managing director of AbCheck in 2009. Prior to founding MedVenture Partners, Dr. Fischer worked with KPMG for more than six years until 2002, where he was responsible for biotech and healthcare assignments. Before joining KPMG, he worked for Deutsche Bank AG. Dr. Fischer is also a member of the audit committee of Amphivena. He holds a graduate degree in business administration from Humboldt University, Berlin and a Ph.D. in public health from the University of Bielefeld.

**Jens-Peter Marschner, Chief Medical Officer.** Dr. Marschner joined us in 2013 from Merck KGaA (Merck Serono). He has 19 years of professional experience in clinical development with a focus on biological compounds. At Merck Serono, Dr. Marschner served as Vice President Immunological Programs Oncology from 2009-2012 and Vice President Global Medical Affairs from 2003-2009, primarily in the field of oncology. Dr. Marschner led the clinical development team of cetuximab (Erbix<sup>®</sup>), a monoclonal antibody to treat colorectal cancer, which was successfully launched in 2004. He started his pharmaceutical career in 1995 at Boehringer Mannheim, which is now

part of Roche. He studied medicine in Jena (Germany), obtained an M.D. in 1991 from Johann-Wolfgang-Goethe-University in Frankfurt and became a board certified specialist in clinical pharmacology in 1995.

**Jörg Windisch, Chief Operating Officer.** Dr. Windisch joined us in 2016 after spending 20 years at Sandoz Biopharmaceuticals (a Novartis company), most recently serving as Chief Science Officer. He joined Novartis in 1996 in the biologics unit of Sandoz, where he played a leading role in the development of Somatropin (Omnitrope®), the first ever biosimilar medicine, as well as of Sandoz' Epoetinalfa (Binocrit®) and Filgrastim (Zarzio®) products. Over the course of 15 years he built an international technical development organization for biologics and for five years Dr. Windisch also led the joint biologics technical development and manufacturing organization for Novartis Pharma and Sandoz. He was involved in the development and manufacturing of about 20 biologics, six of which are currently marketed. Dr. Windisch was educated in Austria, Germany and the U.S. and received his Ph.D. in Biochemistry and Molecular Genetics from the University of Innsbruck.

The following is a brief summary of the business experience of certain other key employees.

**Andrew Curtis, Head of Corporate Strategy and BD, President & CEO Affimed Inc.** Mr. Curtis joined us in 2015 with more than 20 years of expertise in a range of positions in both large pharmaceutical companies, most notably Pfizer, and as a biotechnology entrepreneur, focusing on the licensing, commercial development and commercialization of new medicines for rare and neglected diseases. Mr. Curtis was the Founder and CEO of Rising Tide Therapeutics, a biotech startup focused on developing medicines for genetic pulmonary diseases. Prior to this, Mr. Curtis was CEO of Jerini US Inc., a company focused on the development and commercialization of icatibant, a treatment for hereditary angioedema, subsequently commercialized under the brand name Firazyr by Shire after it acquired Jerini in 2008. His career also includes commercial marketing and sales positions with Pfizer, Genzyme, TargetRx, J&J, and Merck, as well as advisory activities. Mr. Curtis holds a B.A. from Muhlenberg College and a M.A. from Lehigh University.

**Erich Rajkovic, Head of Research Operations and Intellectual Property.** Dr. Rajkovic joined us in 2007 as scientist in antibody discovery and antibody engineering. In 2010, he joined our Business Development team and was promoted to Director of Business Development in 2011. From 2013 to 2016 he was responsible for Business Development & Alliance Management and he became Head of Research Operations and Intellectual Property in 2016. Dr. Rajkovic played a key role in the negotiations with Amphivena and Janssen and with The Leukemia & Lymphoma Society. In addition, Dr. Rajkovic has been leading the negotiations of the cGMP manufacturing and clinical trial agreements. Prior to Affimed Dr. Rajkovic worked for Kwizda Pharma (Austria). He studied pharmacy and received his Ph.D. in protein chemistry and biophysics from the University of Graz (Austria) in 2006.

**Martin Treder, Chief Scientific Officer.** Dr. Treder joined us in 2015 and has 13 years of professional experience in the field of biotherapeutics research and development. Before joining Affimed, he was Chief Scientific Officer at CT Atlantic AG where he was responsible for establishing a broad research pipeline of various preclinical and clinical development programs. Prior to CT Atlantic, Dr. Treder held the position of Program Director at U3 Pharma AG, a German biotech company developing targeted cancer therapeutics, where he headed the company's portfolio of innovative anti-HER3 therapeutic antibodies. Dr. Treder graduated with Honors from Monash University in Melbourne, Australia and obtained a diploma in Biology at the University of Würzburg, Germany. He earned his Ph.D. working in Prof. Axel Ullrich's group at the Max Planck Institute of Biochemistry in Martinsried-Munich, receiving his doctorate from the Technical University of Munich, Germany.

**Claudia Wall, Head of Project Management Regulatory Affairs and Quality Management.** Dr. Wall joined us in 2002 as scientist responsible for the generation and screening of highly diverse antibody libraries. In 2008, Dr. Wall was promoted to Head of Project Management, Regulatory Affairs and Quality Management where she has been responsible for the successful establishment of the cGMP-compliant production processes of both lead projects AFM13 and AFM11. In addition, Dr. Wall managed the successful filings of the respective CTAs and INDs for both programs. Prior to joining Affimed, Dr. Wall worked as a scientific associate from 1997 until 2001 at Hoffmann-LaRoche AG Grenzach-Wyhlen in the neurodegenerative diseases and dermatology unit. She received her undergraduate degree in biology and a Ph.D. from the Institute of Pathobiochemistry and General Neurochemistry at the Faculty of Medicine at Ruprecht-Karls-University in Heidelberg.

**Michael Wolf, Head of Finance and Administration.** Mr. Wolf joined us in 2015 and has responsibility for the Company's finance department including general administration. Prior to joining Affimed, he worked from 2006 to 2014 at SYGNIS AG, Heidelberg, a German listed Biotech company as Director Finance and most recently as Vice



President Finance & Administration. Between 2001 and 2006, Mr. Wolf was employed at Ernst & Young, where he most recently served as Audit Manager for audit and consulting mandates with Biotech companies and private Life Science funds. In 2005, Mr. Wolf has successfully passed the tax consultant exam. From 1996 to 2001, he worked as auditor at the Frankfurt Branch of KPMG. During this time he was involved particularly in audit and consulting mandates for banks and financial institutions across Europe. Mr. Wolf holds a Diploma in Business Administration from Fachhochschule Ludwigschafen.

## **B. Compensation**

### **Management services agreements**

Our managing directors have entered into management services agreements with us. The management services agreements of Adi Hoess, Florian Fischer and Jens-Peter Marschner became effective upon the consummation of our initial public offering. The management services agreement of Jörg Windisch became effective upon his appointment by the general meeting of shareholders on January 21, 2016. 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.

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

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

In conjunction with the closing of our initial public offering, we established the Affirmed 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 1,678,891 common shares. On January 1 of any calendar year thereafter (including January 1, 2016), an additional 5% of the total outstanding common shares on that date becomes available for issuance under the 2014 Plan. 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, but constitutes a deviation from the best practice provisions of the DCGC. As a result, if we engage in re-pricing of stock options, we would be required to provide an explanation in our annual report for why we do not comply with the best practice provisions.

*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.

### Stock Option Equity Incentive Plan 2007

Under the Stock Option Equity Incentive Plan 2007 (the “2007 SOP”), we granted options that were exercisable for preferred shares. In conjunction with the corporate reorganization in connection with our initial public offering, all outstanding awards granted under the 2007 SOP were converted into awards exercisable for common shares of Affimed N.V., and no additional grants will be made under the 2007 SOP. All awards are fully vested. The 2007 SOP is administered by the management board, or with respect to awards to our officers, by the supervisory board. The respective board determines the participants, the amount of the award, the exercise period and any other matters arising under the 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, 2015, 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, 2015. As of December 31, 2015, we have no amounts set aside or accrued to provide pension, retirement or similar benefits to our managing directors and supervisory directors.

### Carve-Out Agreements

Certain of our managing directors and supervisory directors are entitled to receive, or have already received, common shares in connection with the carve-out plan described in Notes 2 and 19 to our consolidated financial statements 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 have been or will be transferred to the beneficiaries upon the conditions set forth therein.

### Directors compensation 2015

#### Managing directors

(in € thousand)	Hoess	Fischer	Marschner	Total
Periodically paid compensation	424	319	319	1,062
Bonuses	149	83	83	315
<b>Total cash compensation</b>	<b>573</b>	<b>402</b>	<b>402</b>	<b>1,377</b>
2014 Plan share-based payment expense	774	298	252	1,324
<b>Total share-based payment expense</b>	<b>774</b>	<b>298</b>	<b>252</b>	<b>1,324</b>

#### Supervisory directors

(in € thousand)	Hecht	Grau	Modig	Stead	Verdonck	Total
Periodically paid compensation	120	24	51	40	61	296
Service fees*	0	138	0	0	0	138
<b>Total cash compensation</b>	<b>120</b>	<b>162</b>	<b>51</b>	<b>40</b>	<b>61</b>	<b>434</b>
2014 Plan share-based payment expense	167	47	88	88	88	478
<b>Total share-based payment expense</b>	<b>167</b>	<b>47</b>	<b>88</b>	<b>88</b>	<b>88</b>	<b>478</b>

\* Ulrich Grau is a significant shareholder and Chairman of the Board of Directors of i-novion Inc., which was engaged by us to conduct preclinical services. In 2015, i-novion Inc. received related payments of €138,000.

**Stock options granted under the Equity Incentive Plan 2014****Managing directors**

<b>Beneficiary</b>	<b>Grant date</b>	<b>Number of options</b>	<b>Strike price USD</b>	<b>Expiration date</b>
Adi Hoess	September 4, 2015	290,000	9.42	September 4, 2025
Florian Fischer	September 4, 2015	105,000	9.42	September 4, 2025
Jens-Peter Marschner	September 4, 2015	80,000	9.42	September 4, 2025
<b>Total</b>		<b>475,000</b>		

**Supervisory directors**

<b>Beneficiary</b>	<b>Grant date</b>	<b>Number of options</b>	<b>Strike price USD</b>	<b>Expiration date</b>
Thomas Hecht	June 9, 2015	20,000	12.44	June 9, 2025
Ulrich M. Grau	July 1, 2015	20,000	13.47	July 1, 2025
Berndt Modig	June 9, 2015	20,000	12.44	June 9, 2025
Richard Stead	June 9, 2015	20,000	12.44	June 9, 2025
Ferdinand Verdonck	June 9, 2015	20,000	12.44	June 9, 2025
<b>Total</b>		<b>100,000</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 of shareholders prior to the consummation of our initial public offering. 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 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 financial and operating goals for the period. The bonus payments may be increased in any given year by the supervisory board upon a proposal of the compensation committee based on any exceptional achievements of that managing director. In addition, the remuneration policy for managing directors allows for cash termination payments, which may not exceed 200% of the managing director's base salary. This policy also allows for additional compensation and benefits to our managing directors following a change of control.

Our remuneration policy for the supervisory directors provides for payments 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 chairman of the audit committee is entitled to an additional annual retainer of €15,000 and the chairmen of the compensation and nomination and corporate governance committees are each entitled to annual retainers of €7,500. Supervisory directors will also be paid €3,000 for each supervisory board meeting attended in person and €1,500 for each supervisory board meeting attended by telephone, provided the meeting attended by telephone exceeds 30 minutes. The members of each committee will be paid €1,500 for each committee meeting attended in person and €750 for each committee meeting attended by telephone, provided the meeting attended by telephone exceeds 30 minutes. In addition, we will grant any future chairman of the supervisory board an initial award of stock options to purchase 35,000 common shares on the date of election as the chairman. Further, under the remuneration policy we

will grant any future supervisory director an initial award of stock options to purchase 20,000 common shares on the date of election as a supervisory director. These initial stock options will vest over a three-year period in three equal installments on the anniversaries of the grant date. In addition, the remuneration policy provides that each supervisory director is entitled to a total annual grant of 10,000 stock options, with the chairman of the supervisory board entitled to an annual grant of 20,000 stock options. These annual awards will vest in four quarterly installments and will be fully vested on the first anniversary of the grant date. Initial awards and annual awards will be granted automatically on the respective dates of issuance based on the approval by the shareholders of the remuneration policy and will not require any further approval 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.

## **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 quarter 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 Ferdinand Verdonck (Chairman), Berndt Modig 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 Ferdinand Verdonck, Berndt Modig and Bernhard R. M. Ehmer satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. The supervisory board has determined that each of Ferdinand Verdonck and Berndt Modig qualifies 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.

#### ***Compensation committee***

The compensation committee, which consists of Thomas Hecht (Chairman), Ulrich Grau and Berndt Modig, assists the supervisory board 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 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.

***Nomination and corporate governance committee***

The nomination and corporate governance committee, which consists of , Thomas Hecht (Chairman), Ulrich Grau and Richard B. Stead, assists our supervisory board in identifying individuals qualified to become members of our supervisory board and management board consistent with criteria established by our supervisory board and in developing our corporate governance principles. 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.

**D. Employees**

As of March 15, 2016, we had 39 personnel (full time equivalents), approximately 70% of whom have an advanced academic degree (Diploma/ Master, PhD, MD). Including AbCheck and Affimed Inc., our total headcount is 64.

None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We have established a workers' council for our employees. 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, 2016, 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.

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, 2016 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 33,259,404 of our common shares outstanding as of March 15, 2016. Common shares that a person has the right to acquire within 60 days of March 15, 2016 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
<b>5% Shareholders</b>		
Entities affiliated with Aeris Capital AG(1)	8,975,598	27.0%
Entities affiliated with OrbiMed Advisors LLC(2)	4,500,641	13.5%
Novo Nordisk A/S(3)	2,734,014	8.2%
Brookside Capital Trading Fund, L.P.(4)	2,097,902	6.3%
<b>Managing Directors and Supervisory Directors</b>		
Adi Hoess(5)	125,000	0.4%
Florian Fischer(5)	50,000	0.2%
Jens-Peter Marschner(5)	45,000	0.1%
Thomas Hecht	62,868	0.2%
Bernhard R.M. Ehmer	5,000	0.0%
Ulrich M. Grau	79,919	0.2%
Berndt Modig	17,500	0.1%
Richard B. Stead	27,090	0.1%
Ferdinand Verdonck	17,500	0.1%
All managing directors and supervisory directors as a group (9 persons)	429,877	1.3%

- (1) Consists of 8,939,924 shares held by SGR Sagittarius Holding AG ("Sagittarius") and 35,674 shares held by AGUTH Holding GmbH ("AGUTH"). Voting and investment power over the shares held by SGR Sagittarius Holding AG is exercised by the Board of Directors of SGR Sagittarius Holding AG, Dr. Johann Irsigler, Manuel Werder and Sonja Frech. The address for SGR Sagittarius Holding AG is Brügglistrasse 2, 8852 Altendorf, Switzerland. Voting and investment power over the shares held by AGUTH is exercised by the Board of Directors of AGUTH, Harald Tschira and Udo Tschira. The address for AGUTH is Schloß-Wolfsbrunnenweg 33, 69118 Heidelberg, Germany. This information is based on a statement filed on Schedule 13D with the SEC on December 17, 2015.
- (2) Consists of 4,458,842 shares held by OrbiMed Private Investments III, LP ("OPI III") and 41,799 shares held by OrbiMed Associates III, LP ("Associates III"). OrbiMed Capital GP III LLC ("GP III") is the general partner of OPI III. OrbiMed Advisors LLC ("OrbiMed") is the managing member of GP III and the general partner of Associates III. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed and may be deemed to have voting and investment power over the shares held by OPI III and Associates III noted above. Each of GP III, Advisors and Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of its or his pecuniary interest therein, if any. The address for OPI III, Associates III, and OrbiMed is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022. This information is based on a statement filed on Schedule 13D with the SEC on March 17, 2016.
- (3) Novo Nordisk A/S is a publicly-held entity whose B shares are listed on the NASDAQ OMX Copenhagen and whose ADRs are listed on the New York Stock Exchange. The address for Novo Nordisk A/S is Novo Allé, DK-2880 Bagsværd, Denmark. This information is based on a statement filed on Schedule 13G with the SEC on February 17, 2015.
- (4) Brookside Capital Trading Fund, L.P. ("Brookside"), is a privately held entity affiliated with Bain Capital LLC. The address for Brookside is Brookside Capital Trading Fund, L.P., John Hancock Tower 200 Cl, Boston, MA 02116. This information is based on a statement filed on Schedule 13G with the SEC on May 13, 2015.
- (5) Indicates that the director is entitled to receive common shares in connection with the carve-out plan described in Notes 2 and 19 to our consolidated financial statements 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

We have experienced significant changes in the percentage ownership held by major shareholders as a result of our initial public offering and subsequent offerings. Immediately prior to our initial public offering in September 2014, our principal shareholders were entities affiliated with Aeris Capital AG (32.2% ownership), entities affiliated with OrbiMed Advisors LLC (30.7% ownership), Novo Nordisk A/S (14.3% ownership), BioMedInvestI Ltd. (9.2% ownership) and entities affiliated with Life Sciences Partners (9.2% ownership).

On September 17, 2014, we completed our initial public offering and listed our common shares on the Nasdaq Global Market. In the initial public offering, we sold 8,000,000 common shares. Certain of our pre-IPO investors purchased approximately \$23.7 million of our common shares in the initial public offering.

On May 12, 2015 we completed a public offering and sold 5,750,000 common shares to new investors.

On October 14, 2015 we sold 3.3 million shares to SGR Sagittarius Holding AG, an existing shareholder affiliated with Aeris Capital AG.

## Holders

As of March 15, 2016, we had approximately 13 shareholders of record of our common stock.

## B. Related party transactions

The following is a description of related party transactions we have entered into since January 1, 2015 with any of our members of our supervisory board or management board and the holders of more than 5% of our common shares.

### Agreements with Supervisory Directors

We had a consulting agreement with Ulrich M. Grau, whose term as a supervisory director became effective as of July 1, 2015. Dr. Grau's remuneration under the agreement consisted of service fees for business development, corporate strategy and the development of new products. In June 2015, this consulting agreement was terminated and all associated rights and obligations ceased. Also, according to a services agreement with i-novion Inc., of which Dr. Grau serves as Chairman of the Board of Directors, i-novion Inc. conducted certain preclinical services for us. In 2015, i-novion Inc. received related payments of €138,000.

### Agreements with Amphivena

In 2013, we entered into a license and development agreement, which amended and restated a 2012 license agreement, with Amphivena Therapeutics, Inc., or Amphivena, based in San Francisco, to develop an undisclosed product candidate for hematologic malignancies in exchange for an interest in Amphivena and certain milestone payments. We have also assigned and licensed certain technology to Amphivena and provided it with funding. See "Item 4. Information on the Company— B. Business overview—Amphivena" and "Item 5. Operating and Financial Review and Prospects—A. Operating Results—Collaboration Agreements—Amphivena" for more information.

### Registration rights agreement

Following the consummation of our IPO, we entered into a registration rights agreement with certain of our existing shareholders pursuant to which we granted them the rights set forth below.

*Demand registration rights.* Certain of our shareholders that are party to the Registration Rights Agreement (the "RRA Shareholders") are entitled to request that we effect up to an aggregate of four demand registrations under the Registration Rights Agreement, and no more than one demand registration within any six-month period, covering the RRA Shareholders' common shares that are subject to transfer restrictions under Rule 144 ("registrable securities"). The demand registration rights are subject to certain customary conditions and limitations, including customary underwriter cutback rights and deferral rights. No demand registration rights exist while a shelf registration is in effect.

*Piggyback registration rights.* If we propose to register any common shares (other than in a shelf registration or on a registration statement on Form F-4, S-4 or S-8), the RRA Shareholders are entitled to notice of such registration and to include their registrable securities in that registration. The registration of RRA Shareholders' registrable securities pursuant to a piggyback registration does not relieve us of the obligation to effect a demand registration. The managing underwriter has the right to limit the number of registrable securities included in a piggyback registration if the managing underwriter believes it would interfere with the successful marketing of the common shares.

*Form F-3 registration rights.* When we are eligible to use Form F-3, one or more RRA Shareholders have the right to request that we file a registration statement on Form F-3. RRA Shareholders will have the right to cause us to undertake underwritten offerings from the shelf registration, but no more than one underwritten offering in a six-month period. Each underwritten takedown constitutes a demand registration for purposes of the maximum number of demand registrations we are obligated to effectuate.



Subject to limited exceptions, the Registration Rights Agreement provides that we must pay all registration expenses in connection with a demand, piggyback or shelf registration. The Registration Rights Agreement contains customary indemnification and contribution provisions.

### **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. See “Item 3. Key Information—D. Risk factors.”

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

We have not declared cash dividends on our common stock in the years 2013, 2014 or 2015. 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. The following table sets forth the high and low sales prices as reported by Nasdaq for each quarter:

	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2015</b>		
First Quarter	\$ 9.16	\$ 5.16
Second Quarter	13.75	5.85
Third Quarter	24.20	5.83
Fourth Quarter	8.42	5.75

**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.

We incorporate by reference into this Annual Report on Form 20-F the description of our Articles of Association effective upon the closing of our IPO contained in our F-1 registration statement (File No. 333-197097) originally filed with the SEC on June 27, 2014, as amended. Such description sets forth a summary of certain provisions of our articles of association as currently in effect.

**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 and the Netherlands and regulations thereunder and on the tax laws of 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 Article 2 of 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 at least a 10% direct stake in the company’s registered capital for one year and to file a respective application with the German Federal Central Tax Office (*Bundeszentralamt für Steuern, Hauptdienstszitz Bonn-Beuel, An der Kuppe 1, 53225 Bonn*) using an official form.

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, 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*).

#### *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*) of €801 (€1,602 for married couples filing jointly). 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 work for the Company in a professional capacity.

##### *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 (*Mitunternehmerschaften*)) 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.

However, the dividends (after deducting business expenses economically related to the dividends) are subject to trade tax in the full amount, unless the requirements of the trade tax participation exemption privilege are fulfilled. 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 prerequisites of the trade tax participation exemption privilege are fulfilled. 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.

*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 €801 (€1,602 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 shares.

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 Wertpapierhandelsunternehmen*) 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) 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. Pursuant to the current view of the German tax authorities (which has recently been rejected by a fiscal court; a decision by the German Federal Tax Court (*Bundesfinanzhof*) is still pending), 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.

#### *Withholding tax*

In case of a Domestic Paying Agent, the capital gains from shares held as business assets are not 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*”). Instead, 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*”), 5% of the gains from the disposal of the shares should currently be subject to corporate income tax plus the solidarity surcharge thereon, if the shareholder is a corporation. If the shareholder is a private individual, 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). However, 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.

#### ***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.

### **Dutch Tax Considerations**

The following does not purport to present a comprehensive or complete description of all aspects of Dutch tax law which could be of relevance to a holder of common shares (a "Shareholder"). For Dutch tax purposes, a Shareholder may include an individual or entity who does not have the legal title of the common shares in the capital of the Company (the "Shares"), but to whom nevertheless the Shares are attributed based either on such individual or entity holding a beneficial interest in the Shares or based on specific statutory provisions, including statutory provisions pursuant to which Shares are attributed 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.

Shareholders or prospective Shareholders should therefore consult their tax adviser regarding the tax consequences of any purchase, ownership or disposal of common Shares in their particular circumstance.

The following summary is based on the Dutch tax law as applied and interpreted by Dutch tax courts and as published and in effect on the date hereof, without prejudice to any amendments introduced at a later date and implemented with or without retroactive effect. For the purpose of this paragraph, "Dutch Taxes" means taxes of whatever nature levied by or on behalf of the Netherlands or any of its subdivisions or taxing authorities. The Netherlands means the part of the Kingdom of the Netherlands that is located in Europe.

Any reference hereafter 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 country of the Netherlands (*Belastingregeling voor het land Nederland*), 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.

### **Withholding Tax**

A Shareholder is generally subject to Dutch dividend withholding tax at a rate of 15% on dividends distributed by the Company. The Company is generally responsible for the withholding of such dividend withholding tax at its source. The dividend withholding tax is for the account of the Shareholder.

On January 1, 2016 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, concluded on April 12, 2012 (the "2012 Germany-Netherlands Treaty"), entered into force. Under the 2012 Germany-Netherlands Treaty, a Shareholder, other than a Shareholder who is a resident of the Netherlands, will not be subject to Dutch dividend withholding tax on dividends distributed by the Company, irrespective of the nature or form of such dividend, if and for as long as the Company is a tax resident solely in Germany for purposes of the 2012 Germany-Netherlands Treaty. A Shareholder that is a resident of the Netherlands, will generally be subject to Dutch dividend withholding tax on dividends distributed by the company, irrespective of the nature or form of such dividend, at a rate of 15%. The Company intends to be a resident solely in Germany for purposes of the 2012 Germany-Netherlands Treaty on a continuous basis.

Dividends distributed by the Company include, but are not limited to:

- § distributions of profits in cash or in kind, deemed or constructive distributions, whatever they might be named or in whatever form;

- § proceeds from the liquidation of the Company, or proceeds from the redemption or the repurchase of Shares by the Company or one of its direct or indirect subsidiaries, other than as a temporary portfolio investment (*tijdelijke belegging*), in excess of the average paid-in capital recognized for Dutch dividend withholding tax purposes;
- § the nominal value of Shares issued to a Shareholder or an increase in the nominal value of the Shares, to the extent that no contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- § partial repayment of paid-in capital, that is
  - § not recognized for Dutch dividend withholding tax purposes, or
  - § recognized for Dutch dividend withholding tax purposes, to the extent that the Company has “net profits” (*zuivere winst*), unless
    - (a) the general meeting of Shareholders has resolved in advance to make such repayment, and
    - (b) the nominal value of the Shares concerned has been reduced with 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.

Notwithstanding the above, no withholding is required in the event of a repurchase of Shares, if certain conditions are fulfilled.

If a Shareholder is resident or deemed to be resident in the Netherlands, such Shareholder is generally entitled to an exemption or a full credit for any Dutch dividend withholding tax against his or her Dutch income or corporate income tax liability and to a refund of any residual Dutch dividend withholding tax. The same generally applies to a Shareholder that neither is resident nor deemed to be resident in the Netherlands if the Shares of the Company are attributable to a Netherlands permanent establishment of such non-resident Shareholder.

If a Shareholder is resident in a country other than the Netherlands, under certain circumstances exemptions from, reductions in or refunds of Dutch dividend withholding tax may be available pursuant to Dutch domestic law or treaties or regulations for the avoidance of double taxation.

According to Dutch domestic anti-dividend stripping rules, no credit against Dutch income or corporate income tax, exemption from, reduction in or refund of, Dutch dividend withholding tax will be granted if the recipient of the dividend paid by the company is not considered to be the beneficial owner (*uiteindelijk gerechtigde*) of such dividend as meant in these rules.

#### ***Taxes on Income and Capital Gains***

This paragraph does not purport to describe the possible Dutch tax considerations or consequences that may be relevant to a Shareholder:

- § who is an individual and for whom the income or capital gains derived from the Shares are attributable to employment activities, the income from which is taxable in the Netherlands;
- § that is an entity that is not subject to corporate income tax in full or is partially exempt from corporate income tax (such as pension funds);
- § that is an investment institution (*beleggingsinstelling*) as defined in Section 6a or 28 of the Dutch 1969 Corporate income tax act (*Wet op de vennootschapsbelasting 1969*, “CITA”); or
- § which is entitled to the participation exemption (*deelnemingsvrijstelling*) with respect to the Shares as defined in Section 13 of CITA.

**Residents in the Netherlands**

The description of certain Dutch tax consequences in this paragraph is only intended for the following Shareholders:

- (a) individuals who are resident or deemed to be resident in the Netherlands for Dutch income tax purposes (“Dutch Individuals”); and
- (b) entities that are subject to the CITA and are resident or deemed to be resident in the Netherlands for corporate income tax purposes (“Dutch Corporate Entities”).

*Dutch Individuals engaged or deemed to be engaged in an enterprise or in miscellaneous activities*

Dutch Individuals are generally subject to income tax at statutory progressive rates with a maximum of 52% (2016) with respect to any benefits derived or deemed to be derived from Dutch Enterprise Shares (as defined below), including any capital gains realized on the disposal thereof.

“Dutch Enterprise Shares” are Shares or any right to derive benefits therefrom:

- § which are attributable to an enterprise from which a Dutch Individual derives profits, whether as an entrepreneur (*ondernemer*) or pursuant to a co-entitlement to the net worth of such enterprise (other than as an entrepreneur or a shareholder); or
- § of which the benefits are taxable in the hands of a Dutch Individual as benefits from miscellaneous activities (*resultaat uit overige werkzaamheden*) including, without limitation, activities which are beyond the scope of active portfolio investment activities (*normaal actief vermogensbeheer*).

*Dutch Individuals holding a substantial interest or fictitious substantial interest*

Dutch Individuals are generally subject to income tax at a statutory rate of 25% (2016) with respect to any benefits derived or deemed to be derived from Shares, excluding Dutch Enterprise Shares, (including any capital gains realized on the disposal thereof), that are attributable to a substantial interest or fictitious substantial interest (such shares being “Substantial Interest Shares”).

Generally, a Shareholder has a substantial interest (*aanmerkelijk belang*) in the Company if such Shareholder, alone or together with his or her partner, directly or indirectly:

- § owns, or holds certain rights on, Shares representing 5% or more of the total issued and outstanding capital of the Company, or of the issued and outstanding capital of any class of shares of the Company;
- § holds rights to acquire Shares, whether or not already issued, representing 5% or more of the total issued and outstanding capital of the Company, or of the issued and outstanding capital of any class of shares of the Company; or
- § owns, or holds certain rights on, profit participating certificates that relate to 5% or more of the annual profit of the Company or to 5% or more of the liquidation proceeds of the Company.

Generally, a Shareholder has a fictitious substantial interest (*fictief aanmerkelijk belang*) in the Company if, without having an actual substantial interest in the Company:

- § an enterprise has been contributed to the Company in exchange for Shares on an elective non-recognition basis;
- § Shares have been obtained under gift law, inheritance law or matrimonial law, on a non-recognition basis, while the previous holder had a substantial interest in the Company;
- § Shares have been acquired pursuant to a share merger, legal merger or legal demerger, on an elective non-recognition basis, while the holder prior to this transaction had a substantial interest in an entity that was party thereto; or

- § Shares held by the holder, prior to dilution, qualified as a substantial interest and, by election, no gain was recognized upon disqualification of these Shares.

A Shareholder will also have a substantial interest if its partner or one of certain defined relatives of the Shareholder or of its partner has a substantial interest.

*Dutch Individuals not engaged or deemed to be engaged in an enterprise or in miscellaneous activities or having a substantial interest or fictitious substantial interest*

Generally, a Dutch Individual who owns Shares, excluding Dutch Enterprise Shares, will be subject annually to an income tax imposed on a fictitious yield on such Shares 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 of all the assets and liabilities of a Dutch Individual that are taxed under this regime, including the Shares is set at a fixed amount. The fixed amount equals 4% of the fair market value of the assets reduced by the liabilities and measured, in general, exclusively at the beginning of every calendar year. The tax rate under the regime for savings and investments is a flat rate of 30% (2016), with a tax free allowance of €24,437 (2016).

*Dutch Corporate Entities*

Dutch Corporate Entities are generally subject to corporate income tax at statutory rates up to 25% with respect to any benefits derived or deemed to be derived (including any capital gains realized on the disposal) of Shares.

***Non-residents in the Netherlands***

A Shareholder other than a Dutch Individual or Dutch Corporate Entity, will not be subject to any Dutch Taxes on income or capital gains with respect to the ownership and disposal or deemed disposal of the Shares, other than dividend withholding tax as described above, except if:

- § the Shareholder, whether an individual or not, derives profits from an enterprise, whether as an entrepreneur or pursuant to a co-entitlement to the net worth of such enterprise other than as an entrepreneur or a shareholder, 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;
- § the Shareholder is an individual and derives benefits from miscellaneous activities carried out in the Netherlands in respect of the Shares, including, without limitation, activities which are beyond the scope of active portfolio investment activities;
- § the Shareholder is an individual and has a substantial interest or a fictitious substantial interest in the company, which substantial interest or fictitious substantial interest is not attributable to the assets of an enterprise;
- § the Shareholder is not an individual and has a substantial interest or a fictitious substantial interest in the Company, which substantial interest or fictitious substantial interest is not attributable to the assets of an enterprise and the main or one of the main purposes of the chosen ownership structure is the evasion of Dutch income tax or dividend withholding tax;
- § the Shareholder is an individual and is entitled to a share in the profits of an enterprise, other than by way of the holding of securities, which enterprise is effectively managed in the Netherlands and to which enterprise the Shares are attributable;
- § the Shareholder is not an individual and 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 the holding of securities, which enterprise is effectively managed in the Netherlands and to which enterprise the Shares are attributable; or
- § the Shareholder is not an individual, is resident of Aruba, Curacao, or Sint Maarten and derives profits from an enterprise, which enterprise is, in whole or in part, carried on through a permanent establishment or a permanent representative on Bonaire, Sint Eustatius or Saba, to which the Shares are attributable.

However, if and for as long as the Company is a tax resident solely in Germany for the purposes of the 2012 Germany-Netherlands Treaty, a Shareholder other than a Dutch Individual or Dutch Corporate Entity, who holds a substantial interest or a fictitious substantial interest in the Company will not be subject to Dutch Taxes on income or capital gains in respect of the ownership and disposal of the Shares.

### ***Gift Tax and Inheritance Tax***

No Dutch gift 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, except if:

- § at the time of the gift or death of the Shareholder, the Shareholder is resident, or is deemed to be resident, in the Netherlands;
- § the Shareholder passes away within 180 days after the date of the gift of the Shares and is not, or not deemed to be, at the time of the gift, but is, or deemed to be, at the time of his or her death, resident in the Netherlands;
- § 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; or
- § the transfer of the Shares is otherwise construed as a gift or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident in the Netherlands.

For purposes of Dutch gift or inheritance tax, an individual who is of Dutch nationality will be deemed to be resident in the Netherlands if such individual has been resident in the Netherlands at any time during the ten years preceding the date of the gift or his or her death. For purposes of Dutch gift tax, any individual, irrespective of his or her nationality, will be deemed to be resident in the Netherlands if he or she has been resident in the Netherlands at any time during the 12 months preceding the date of the gift.

### ***Other Taxes and Duties***

No Dutch value added tax or Dutch taxes of a documentary nature, such as stamp or registration tax or other similar tax or duty, are payable by or on behalf of a Shareholder by reason only of the purchase, ownership and disposal of the Shares.

### ***Residency***

A Shareholder will not become resident, or deemed resident, in the Netherlands for tax purposes by reason only of holding the Shares.

### **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 hold the common shares.

This discussion applies only to a U.S. Holder that holds common shares as capital assets for tax purposes. In addition, it does not describe all of the 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 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 voting shares;
- § persons who acquired our common shares pursuant to the exercise of an employee stock option or otherwise as compensation; 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 generally depend on the status of the partner and the activities of 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 discussion is based on the Internal Revenue Code of 1986, as amended (the “Code”), administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Germany and the United States (the “Treaty”) all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect.

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 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.

### ***Taxation of Distributions***

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 generally 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). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations and the passive foreign investment company rules described below, 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 certain non-corporate U.S. Holders will be eligible for taxation as “qualified dividend income” and therefore will be taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holders. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. The amount of a dividend will include any amounts withheld by us in respect of German income taxes. The amount of the dividend generally will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. 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. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. 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, some of which vary depending upon the U.S. Holder's particular circumstances, German income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. German taxes withheld in excess of the rate applicable under the Treaty will not be eligible for credit against a U.S. Holder's federal income tax liability. See "German Tax Considerations – Taxation of Dividends" for a discussion of how to obtain the applicable treaty rate. 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, at their election, deduct foreign taxes, including any German income 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.

### ***Sale or Other Disposition of Common Shares***

Subject to the passive foreign investment company rules described below, for U.S. federal income tax purposes 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 deductibility of capital losses is subject to various limitations.

### ***Passive Foreign Investment Company Rules***

Under 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. We believe that we were not a PFIC for U.S. federal income tax purposes for our 2015 taxable year based on (i) certain assumptions regarding the classification of our income and assets for PFIC purposes; and (ii) certain estimates as to the value of our assets, including the implied value of our assets based on our market capitalization on certain dates. However, there can be no assurance that the IRS will agree with this conclusion. In addition, whether we will be a PFIC in 2016 or any future years is uncertain because, among other things, (i) we currently own a substantial amount of passive assets, including cash, (ii) 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 (iii) a decline in our market capitalization from levels experienced in 2015 may imply a value of our assets (other than cash) that could lead us to conclude that we are a PFIC for 2016 or for a future year. Accordingly, there can be no assurance that we will not be a PFIC for 2016 or for any other future taxable year. If we are a PFIC for any year during which a U.S. Holder holds common shares, we generally 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.

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 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 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.

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. If a U.S. Holder makes the mark-to-market election, it generally 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 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 in their particular circumstances.

In addition, in order to avoid the application of the foregoing rules, a United States person that owns stock in a PFIC for U.S. federal income tax purposes may make a "qualified electing fund" election (a "QEF Election") with respect to such PFIC if the PFIC provides the information necessary for such election to be made. If a United States person makes a QEF Election with respect to a PFIC, the United States person will be taxed 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. We do not intend to provide information necessary for U.S. Holders to make QEF Elections.

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 it paid a dividend or for the prior taxable year, the preferential dividend rates discussed above 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 holder generally 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, generally with the holder's federal income tax return for that year.

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 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. You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, 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**

We are not subject to any significant 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**

**E. Use of Proceeds**

On September 17, 2014, we completed our initial public offering of our common shares pursuant to a Registration Statement on Form F-1, as amended (File No. 333-197097) that was declared effective on September 12, 2014. Under the registration statement, we sold an aggregate of 8,000,000 common shares. All of these common shares were sold at a price to the public of US\$7.00 per share, yielding gross proceeds of \$56.0 million or net proceeds of \$52.1 million after underwriting discounts and commissions. Jefferies LLC, Leerink Partners LLC and BMO Capital Markets Corp. were joint book-running managers for the initial public offering. We paid the offering expenses in connection with the initial public offering, which were approximately \$3.0 million, and which included SEC registration fees, FINRA filing fees, NASDAQ listing fees and expenses, legal fees and expenses, printing and engraving expenses, accounting fees and expenses as well as other miscellaneous fees and expenses, but excluded the underwriting discounts and commissions.

Between the effective date of the Registration Statement and December 31, 2015, we used approximately \$12 million of the net proceeds to fund research and development expenses for AFM13, AFM11 and AFM21. None of the net proceeds (other than compensation to our management board and supervisory board as disclosed in this Annual Report) were used to make payments, directly or indirectly, to (i) any of our directors, officers or their associates, (ii) any persons owning 10% or more of our common shares or (iii) any of our affiliates. The intended

use of these proceeds has not changed from the information mentioned in the prospectus relating to the Registration Statement.

## **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, 2015.

### **C. Attestation Report of the Registered Public Accounting Firm**

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided to emerging growth companies under the JOBS Act.

### **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, 2015 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 Ferdinand Verdonck and Berndt Modig 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 which 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 published our Code of Conduct on our website, [www.affimed.com](http://www.affimed.com).

#### **ITEM 16C. Principal Accountant Fees and Services**

##### **a) Audit Fees**

Audit fees in 2015 amounted to €322,000 and relate to audit services provided by our principal accountants in 2015, KPMG AG Wirtschaftsprüfungsgesellschaft and other KPMG International member firms, in connection with the audit of the consolidated financial statements and statutory audits, quarterly reviews, review of registration statements and comfort letters for the Company. Audit fees in 2014 amounted to €663,000 and relate to audit services provided by our principal accountants in 2014, KPMG AG Wirtschaftsprüfungsgesellschaft, in connection with the audit of multiple years, quarterly reviews, review of registration statements and comfort letters for the Company. The aggregate audit fees include fees billed or accrued for professional services rendered by the principal accountant for the audit of our annual financial statements and review of the interim condensed consolidated financial statements and additional services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements, except for those not required by statute or regulation.

##### **b) Audit-Related Fees**

None.

##### **c) Tax Fees**

None.

##### **d) All Other Fees**

Other fees in 2015 amounted to €14,000 and relate to consulting services provided by our principal accountants in 2015, KPMG AG Wirtschaftsprüfungsgesellschaft for the implementation of internal controls.

##### **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 in accordance with the Audit Committee's pre-approval policy.

##### **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 2015, 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.

*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.

**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	Articles of Association of Affimed N.V. (incorporated by reference to exhibit 3.1 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on September 17, 2014)
2.1	Registration Rights Agreement between Affimed N.V. and the shareholders listed therein (incorporated by reference to exhibit 4.1 of the Affimed N.V. report on Form 6-K (Registration no. 001-36619) filed with the Commission on September 22, 2014).
4.1†	License Agreement, dated September 29, 2006 between Affimed Therapeutics AG and XOMA Ireland Limited (incorporated by reference to exhibit 10.1 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).
4.2†	License Agreement, dated March 8, 2001 between Affimed Therapeutics AG and Deutsches Krebsforschungszentrum (DKFZ) (incorporated by reference to exhibit 10.2 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).
4.3	Memorandum of Clarification of License Agreement Signed Between Affimed Therapeutics AG and Deutsches Krebsforschungszentrum (DKFZ), dated March 8, 2001 (incorporated by reference to exhibit 10.3 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).
4.4†	Amendment to License Agreement, dated June 13, 2006 between Affimed Therapeutics AG and Deutsches Krebsforschungszentrum (DKFZ) (incorporated by reference to exhibit 10.4 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).
4.5†	Amended and Restated License and Development Agreement dated July 11, 2013 between Affimed Therapeutics AG and Amphivena Therapeutics, Inc. (incorporated by reference to exhibit 4.5 of the Affimed N.V. Annual Report on Form 20-F for the year ended December 31, 2014 (File no. 001-36619) filed with the Commission on March 25, 2015).
4.6†	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).
4.7†	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).
4.8	English language summary of Lease Agreement, dated September 19, 2000 and amendments thereto between Affimed Therapeutics AG and Technologiepark Heidelberg II GmbH & 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).
4.9	Lease Contract dated October 1, 2009, between Abcheck s.r.o. and Vědeckotechnický park Plzeň a.s. (incorporated by reference to exhibit 10.9 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).
4.10	Amendment No. 4 to Lease Contract dated October 1, 2009, between Abcheck s.r.o. and Vědeckotechnický park Plzeň a.s., dated June 30, 2011 (incorporated by reference to exhibit 10.10 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).
4.11	Amendment No. 5 to Lease Contract dated October 1, 2009, between Abcheck s.r.o. and Vědeckotechnický park Plzeň a.s., dated November 14, 2012 (incorporated by reference to exhibit 10.11 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on June 27, 2014).

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4.12	Investment Agreement Series D Round of Financing, Affimed Therapeutics AG, Heidelberg, Germany, dated September 24, 2012 (incorporated by reference to exhibit 10.12 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on August 19, 2014).
4.13	Investment Agreement Pre-IPO Financing, Affimed Therapeutics AG, Heidelberg, Germany, dated June 24, 2014 (incorporated by reference to exhibit 10.13 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on August 19, 2014).
4.14	Convertible Bridge Loan Agreement, dated June 28, 2013 by and between the shareholders party thereto and Affimed Therapeutics AG (incorporated by reference to exhibit 10.14 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on August 19, 2014).
4.15	Amendment to Investment Agreement Pre-IPO Financing, Affimed Therapeutics AG, Heidelberg, Germany (incorporated by reference to exhibit 10.15 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on August 19, 2014).
4.16	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).
4.17	Term Facility Agreement between Affimed Therapeutics AG (now Affimed GmbH) and PCOF 1, LLC dated as of 24 July 2014 (incorporated by reference to exhibit 10.17 of the Affimed N.V. registration statement on Form F-1 (Registration no. 333-197097) filed with the Commission on August 19, 2014).
4.18*	Amendment No. 1 to Term Facility Agreement, dated April 29, 2015 between Affimed GmbH and Perceptive Credit Opportunities Fund, LP.
4.19*	Amendment No. 2 to Term Facility Agreement, dated August 14, 2015 between Affimed GmbH and Perceptive Credit Opportunities Fund, LP.
4.20*	Letter Agreement with respect to Term Facility Agreement, dated March 29, 2016 between Affimed GmbH and Perceptive Credit Opportunities Fund, LP.
8.1	List of subsidiaries. (incorporated by reference to exhibit 8.1 of the Affimed N.V. Annual Report on Form 20-F for the year ended December 31, 2014 (File no. 001-36619) filed with the Commission on March 25, 2015).
12.1*	Certification of Adi Hoess pursuant to 17 CFR 240.13a-14(a).
12.2*	Certification of Florian Fischer pursuant to 17 CFR 240.13a-14(a).
13.1*	Certification of Adi Hoess pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350.
13.2*	Certification of Florian Fischer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350.
15.1*	Consent of KPMG AG Wirtschaftsprüfungsgesellschaft.

\* Filed herewith

† 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

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form 20-F and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Heidelberg, Germany on March 30, 2016.

AFFIMED N.V.

By: /s/ Adi Hoess

Name: Adi Hoess

Title: Chief Executive Officer

By: /s/ Florian Fischer

Name: Florian Fischer

Title: Chief Financial Officer

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Supervisory Board  
Affimed N.V.

We have audited the accompanying consolidated statements of financial position of Affimed N.V. (the "Company") as of December 31, 2015 and 2014, and 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, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Affimed N.V. as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2015 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ KPMG AG Wirtschaftsprüfungsgesellschaft

Leipzig, Germany  
March 16, 2016

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

	Note	2013	2014	2015
<b>Revenue</b>	6	<b>5,087</b>	<b>3,382</b>	<b>7,562</b>
Other income – net	7	610	381	651
Research and development expenses	8	(14,354)	(9,595)	(22,008)
General and administrative expenses	9	(7,046)	(2,346)	(7,548)
<b>Operating (loss)</b>		<b>(15,703)</b>	<b>(8,178)</b>	<b>(21,343)</b>
<b>Finance income / (costs) - net</b>	11	<b>(10,397)</b>	<b>7,753</b>	<b>1,104</b>
<b>Loss before tax</b>		<b>(26,100)</b>	<b>(425)</b>	<b>(20,239)</b>
Income taxes	12	1	166	0
<b>Loss for the period</b>		<b>(26,099)</b>	<b>(259)</b>	<b>(20,239)</b>
<b>Comprehensive loss</b>		<b>(26,099)</b>	<b>(259)</b>	<b>(20,239)</b>
<hr/>				
<b>Loss per share in € per share</b> <b>(undiluted = diluted)</b>		<b>(1.76)</b>	<b>(0.01)</b>	<b>(0.71)</b>

The Notes are an integral part of these consolidated financial statements.

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

	Note	December 31, 2014	December 31, 2015
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	13	72	72
Leasehold improvements and equipment	14	974	915
		<u>1,046</u>	<u>987</u>
<b>Current assets</b>			
Inventories	15	199	228
Trade and other receivables	16	939	915
Other assets	17	0	452
Cash and cash equivalents		39,725	76,740
		<u>40,863</u>	<u>78,335</u>
<b>TOTAL ASSETS</b>		<b>41,909</b>	<b>79,322</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Issued capital		240	333
Capital reserves		131,544	187,169
Accumulated deficit		(99,989)	(120,228)
<b>Total equity</b>	18	<b>31,795</b>	<b>67,274</b>
<b>Non current liabilities</b>			
Borrowings	20	3,895	3,104
<b>Total non-current liabilities</b>		<b>3,895</b>	<b>3,104</b>
<b>Current liabilities</b>			
Trade and other payables	21	3,759	4,444
Borrowings	20	0	1,472
Deferred revenue	6	2,460	3,028
<b>Total current liabilities</b>		<b>6,219</b>	<b>8,944</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>41,909</b>	<b>79,322</b>

The Notes are an integral part of these consolidated financial statements.

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

	Note	2013	2014	2015
<b>Cash flow from operating activities</b>				
Loss for the period		(26,099)	(259)	(20,239)
Adjustments for the period:				
- Income taxes	12	(1)	(166)	0
- Depreciation and amortisation	13, 14	427	441	336
- Loss from disposal of leasehold improvements and equipment	13, 14	24	3	0
- Share based payments	19	8,054	(4,891)	2,220
- Finance income / costs - net	11	10,397	(7,753)	(1,104)
		(7,198)	(12,625)	(18,787)
Change in trade and other receivables	16	(333)	62	24
Change in inventories	15	(20)	(59)	(29)
Change in other assets	17	0	0	(452)
Change in trade and other payables	21	1,880	2,275	1,253
Cash used in operating activities		(5,671)	(10,347)	(17,991)
Interest received		9	2	10
Paid interest		(16)	(202)	(554)
<b>Net cash used in operating activities</b>		<b>(5,678)</b>	<b>(10,547)</b>	<b>(18,535)</b>
<b>Cash flow from investing activities</b>				
Purchase of intangible assets	13	(23)	(45)	(28)
Purchase of leasehold improvements and equipment	14	(139)	(260)	(249)
Proceeds from sale of equipment		5	7	0
<b>Net cash used for investing activities</b>		<b>(157)</b>	<b>(298)</b>	<b>(277)</b>
<b>Cash flow from financing activities</b>				
Proceeds from issue of common shares	18	0	43,213	56,615
Transactions costs related to issue of common shares	18	0	(5,343)	(3,117)
Proceeds from issue of preferred shares		0	2,999	0
Proceeds from convertible debt		5,100	0	0
Transactions costs related to preferred shares and convertible debt		(16)	0	0
Proceeds from borrowings		0	4,020	0
<b>Cash flow from financing activities</b>		<b>5,084</b>	<b>44,889</b>	<b>53,498</b>
<b>Net changes to cash and cash equivalents</b>		<b>(751)</b>	<b>34,044</b>	<b>34,686</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>4,902</b>	<b>4,151</b>	<b>39,725</b>
<b>Exchange-rate related changes of cash and cash equivalents</b>		<b>0</b>	<b>1,530</b>	<b>2,329</b>
<b>Cash and cash equivalents at the end of the period</b>		<b>4,151</b>	<b>39,725</b>	<b>76,740</b>

The Notes are an integral part of these consolidated financial statements.

**Affimed N.V.**  
**Consolidated statement of changes in equity**  
**(in € thousand)**

	Note	Issued capital	Capital reserves	Own shares	Accumulated deficit	Total equity
<b>Balance as of January 1, 2013</b>		<b>63</b>	<b>469</b>	<b>(25)</b>	<b>(73,631)</b>	<b>(73,124)</b>
Loss for the period					(26,099)	(26,099)
<b>Balance as of December 31, 2013</b>		<b>63</b>	<b>469</b>	<b>(25)</b>	<b>(99,730)</b>	<b>(99,223)</b>
<b>Balance as of January 1, 2014</b>		<b>63</b>	<b>469</b>	<b>(25)</b>	<b>(99,730)</b>	<b>(99,223)</b>
Exchange of preferred shares		97	84,907	25		85,029
Issue of common shares	18	80	37,791			37,871
Modification of cash-settled share based payment awards	2		7,648			7,648
Equity-settled share based payment awards	19		299			299
Issue of warrant note (Perceptive loan)	20		430			430
Loss for the period					(259)	(259)
<b>Balance as of December 31, 2014</b>		<b>240</b>	<b>131,544</b>	<b>0</b>	<b>(99,989)</b>	<b>31,795</b>
<b>Balance as of January 1, 2015</b>		<b>240</b>	<b>131,544</b>	<b>0</b>	<b>(99,989)</b>	<b>31,795</b>
Issue of common shares	18	91	52,463			52,554
Exercise of share based payment awards	19	2	942			944
Equity-settled share based payment awards	19		2,220			2,220
Loss for the period					(20,239)	(20,239)
<b>Balance as of December 31, 2015</b>		<b>333</b>	<b>187,169</b>	<b>0</b>	<b>(120,228)</b>	<b>67,274</b>

The Notes are an integral part of these consolidated financial statements.

## 1. Reporting entity

Affimed N.V. (in the following Affimed or Company) is a Dutch company with limited liability (naamloze vennootschap) and has its corporate seat in Amsterdam, the Netherlands. The Company was founded as Affimed Therapeutics B.V. on May 14, 2014 as private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) for a purpose of a corporate reorganization of Affimed Therapeutics AG and converted its legal form under Dutch law to a public company with limited liability for an initial public offering of its common shares.

The consolidated financial statements of Affimed as of and for the year ended December 31, 2015 comprise the Company and its wholly owned and controlled subsidiaries Affimed GmbH, Heidelberg, Germany (former Affimed Therapeutics AG), AbCheck s.r.o., Plzen, Czech Republic and Affimed Inc., Delaware, USA. Financial information presented in the consolidated financial statements for periods prior to the consummation of the corporate reorganization on September 17, 2014 is that of Affimed GmbH and its subsidiary AbCheck s.r.o. Affimed N.V. had not conducted any operations and had not held any assets or liabilities, including contingent liabilities, prior to the reorganization. Affimed Inc. was formed in February 2015 and provides internal services for the Group.

Affimed is a clinical-stage biopharmaceutical group focused on discovering and developing targeted cancer immunotherapies. The Company's product candidates are developed in the field of immuno-oncology, which represents an innovative approach to cancer research that seeks to harness the body's own immune system to fight tumor cells. Affimed has own research and development programs and collaborations, where the Company is performing research services for third parties.

## 2. Corporate Reorganization as of September 17, 2014

At the initial step of the corporate reorganization, the shareholders of Affimed Therapeutics AG subscribed for 15,984,168 common shares in Affimed Therapeutics B.V and agreed to transfer their common shares and their preferred shares in Affimed Therapeutics AG to Affimed Therapeutics B.V in consideration therefore. Simultaneously, the share in Affimed Therapeutics B.V. held by Stichting Affimed Therapeutics was cancelled, and as a result, Affimed Therapeutics AG became a wholly owned subsidiary of Affimed Therapeutics B.V. The legal form of Affimed Therapeutics B.V. was converted from a Dutch private company with limited liability to a Dutch public Company with limited liability, which resulted in a name change into Affimed N.V.

In conjunction with the corporate reorganization, the outstanding awards granted under the Stock Option Equity Incentive Plan 2007 (ESOP 2007) as well as under the carve-out plan, were converted into awards exercisable for common shares of Affimed N.V. The carve-out plan granted the right to receive a cash payment equal to a certain percentage of the fair value of Affimed Therapeutics AG upon the occurrence of a defined exit event.

The securities of Affimed Therapeutics AG were exchanged for common shares of Affimed B.V. according to the following ratios:

- (i) Common shares and Series D preferred shares on an one-to 7.54 ratio except for shares held by a less than 5% shareholder, which were exchanged on a one- to 15.46 basis;
- (ii) Series E preferred shares on a one-to-13.70 basis;
- (iii) ESOP 2007 awards into awards exercisable for common shares of Affimed N.V. on a one-to 7.54 basis.

The carve-out plan provided for a transfer to the grantees of 7.78% of the common shares of the Company owned by the pre-IPO shareholders of the Company at the expiration of the lock up agreements entered into in connection with the IPO. As a result of the consummation of the corporate reorganization, the Company is no longer obliged to deliver cash or common shares to the grantees under the carve-out plan.

The conversion of preferred shares in Affimed Therapeutics AG that had been classified as liability into common shares of Affimed N.V. resulted in a gain of €4,835 recognized as finance income.

### **3. 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 management board on March 16, 2016.

#### **Basis of measurement**

The consolidated financial statements have been prepared on the historical cost basis. The Group did not opt for a valuation of liabilities at fair value through profit or loss.

#### **Consolidation**

The Company controls an entity when the Company 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 transferred to the Company. It is de-consolidated from the date control ceases.

Intercompany transactions, balances and unrealized gains on transactions between group companies are eliminated.

#### **Functional and presentation currency**

These consolidated financial statements are presented in euro, which is also the subsidiaries' functional currency. All financial information presented in euro has been rounded to the nearest thousand (abbreviated €) or million (abbreviated € million).

#### **Presentation of consolidated statement of comprehensive loss**

The line items include revenue, research and development expenses and general and administrative expenses. Cost of sales and gross profit are not meaningful measures for Affimed as a clinical-stage biopharmaceutical company with a focus on research and development activities. All expenses with regards to own research and development and collaboration and research service agreements are presented in research and development expenses.

#### **4. Significant accounting policies**

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements.

##### **Current and non-current distinction**

Affimed presents current and non-current assets and current and non-current liabilities as separate classifications in the statement of financial position. Affimed classifies all amounts expected to be recovered or settled within twelve months after the reporting period as current and all other amounts as non-current.

##### **Foreign currency transactions**

Transactions in foreign currencies are translated to euro at exchange rates at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated to euro at the exchange rate at the reporting date.

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.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction.

Foreign exchange gains or losses that relate to borrowings and cash and cash equivalents 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/expenses – net'.

##### **Notes to the cash flow statement**

The cash flow statement has been prepared using the indirect method for cash flows from operating activities. The cash disclosed in the cash flow statement is comprised of cash and cash equivalents. Cash comprises cash on hand and demand deposits. Cash equivalents are short-term bank deposits and are not subject to a significant risk of changes in value. Interest paid and received is included in the cash flow from operating activities.

##### **Revenue recognition**

The Group licenses its intellectual property to third parties that use the intellectual property to develop product candidates and provides related research and development services to those parties or provides research services based on intellectual property provided by the customer for those services. The research services are performed on a "best efforts" basis without a guarantee of technological or commercial success.



Collaboration and license agreements are evaluated to determine whether they involve multiple elements that can be considered separate units of accounting. To date, the Group has not licensed or sold its intellectual property without continuing involvement by providing the related research and development services. Accordingly, the deliverables under the Group's collaboration and license agreements have not qualified as separate units of accounting.

Revenue from collaborative or other research service agreements is recognized according to the stage of completion.

Non-refundable upfront licensing fees, research funding or technology access fees that have generally no stand-alone value to the customer and require continuing involvement in the form of research and development services or other efforts by the Group are recognized as revenue over the term of the service agreement which is the period of performance.

Milestone payments are contingent upon the achievement of contractually stipulated targets. The achievement of these milestones depends largely on meeting specific requirements laid out in the collaboration and license agreements. Consideration that is contingent upon achievement of a milestone is recognized in its entirety as revenue in the period in which the milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the agreement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must (i) be commensurate with either the Group's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Group's performance to achieve the milestone, (ii) relate solely to past performance, and (iii) be reasonable relative to all deliverables and payment terms in the collaboration agreement.

### **Research and development**

Research expenses are recognized as expenses when incurred. Costs incurred on development projects are recognized as intangible assets as of the date as of which 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 products, no development expenditures have yet been capitalized. Intellectual property-related costs for patents are part of the expenditure for the research and development projects. Therefore, registration costs for patents are expensed when incurred as long as the research and development project concerned does not meet the criteria for capitalization.

As part of the process of preparing the consolidated financial statements Affimed is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on its behalf, estimating the level of service performed and the associated cost incurred for the service when Affimed has not yet been invoiced or otherwise notified of the actual cost. The majority of Affimed's service providers invoice monthly in arrears for services performed or when contractual milestones are met. Affimed makes estimates of its accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to it at that time. Affimed periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary.

## **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.

A liability is recognized for the amount expected to be paid under a short-term cash bonus, if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee, and the obligation can be estimated reliably.

### (ii) Share-based payment transactions

The Company's share-based payment awards outstanding as of December 31, 2014 and 2015 are classified as equity-settled share-based payment plans. 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. Fair value 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 number of stock options expected to vest is estimated at each measurement date.

Prior to the corporate reorganization, all share-based payment awards were classified as cash-settled awards. They were measured based on the services received and the fair value of the liability. Until the cash-settled awards were converted into equity-settled awards in the corporate reorganization (see note 2), the related liability was re-measured at fair value up to the modification date with any changes in fair value recognized in comprehensive loss for the period.

## **Government grants**

The Group receives certain government grants that support its research effort in defined projects. These grants generally provide for 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' in the consolidated statement of comprehensive loss.

## **Lease payments**

Payments made under operating leases are recognized in profit or loss on a straight-line basis over the term of the lease.

## **Finance income and finance costs**

Finance income comprises interest income from interest bearing bank deposits. Interest income is recognized as it accrues in profit or loss, using the effective interest method.

Finance costs comprise interest expense on borrowings and fair value adjustments of embedded derivative conversion features. Borrowing costs are recognized in profit or loss using the effective interest method.

## **Intangible assets**

Intangible assets comprise mainly purchased technology licenses and software. Intangible assets are initially measured at acquisition cost, including any directly attributable costs of preparing the asset for its intended use less accumulated amortization. Amortization begins when an asset is available for use and amortization is calculated using the straight-line method to allocate their cost over their estimated useful lives, as follows:

- Technology licenses: 3-14 years
- Software: 3 years

The Group only owns intangible assets with a definite useful life.

The useful lives of intangible assets are reviewed at each reporting date. The effect of any adjustment to useful lives is recognized prospectively as a change of accounting estimate.

## **Leasehold improvements and equipment**

Leasehold improvements and equipment comprise mainly leasehold improvements, laboratory equipment and other office equipment. Leasehold improvements and equipment are stated at historical cost less accumulated depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

All repairs and maintenance are charged to profit or loss during the financial period in which they are incurred, because it does not constitute a separate asset.

Depreciation on leasehold improvements and equipment is calculated using the straight-line method to allocate their cost over their estimated useful lives, as follows:

- Leasehold improvements: 8-10 years
- Equipment: 3-14 years

Leasehold improvements are depreciated over the shorter of the expected lease term for the buildings the assets relate to or the estimated useful life.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized within other income - net in the consolidated statement of comprehensive loss.

## **Inventories**

Inventories are measured at the lower of cost or net realizable value and comprise chemical substances and other consumables used for research and development. The cost of inventories is based on the average cost-principle and includes expenditure incurred in acquiring the inventories, import duties, as well as transport and other costs directly attributable to the purchase.

## **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 only class of non-derivative financial assets is trade and other receivables and cash and cash equivalents.

Receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets and measured as loans and receivables (see note 16). Loans and receivables are subsequently carried at amortized cost using the effective interest method.

Cash and cash equivalents comprise cash balances and call deposits with original maturities of three months or less.

### **(ii) Non-derivative financial liabilities**

The Group's classes of financial liabilities are borrowings, trade and other payables and, prior to the corporate reorganization, convertible loans and preferred shares. 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 Company entered into the Perceptive loan agreement pursuant to which it issued warrants to purchase common shares of the Company at the option of the holder (see note 20). The number of shares to be issued does not vary with changes in their fair value.

The liability component of the Perceptive loan agreement was recognized initially at the fair value of a similar liability that did not have 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 is measured at amortized cost using the effective interest method. The equity component is not re-measured subsequent to initial recognition except on conversion or expiry.

(iv) Embedded derivatives

Embedded derivatives are separated from the host contract and accounted for as a derivative if the economic characteristics and risks of the embedded derivative are not closely related to the economic characteristics and risks of the host contract. Prior to the corporate reorganization, the conversion features into Series D preferred shares included in the convertible loan issued in 2012 and into Series D or the highest class of preferred shares included in the convertible loan issued in 2013 were embedded derivatives. The Group measured the fair value of the embedded derivative on initial recognition as the difference between the fair value of the hybrid instrument and the fair value of the host contract - the loan. The initial recognition amount of the host contract was calculated as the difference between the issuance price and the fair value of the embedded derivative. The fair value of the host contract was derived from quoted third party offers for similar loans without a conversion feature. Subsequently, the embedded derivatives were measured at fair value through profit or loss with reference to the fair value of Series D preferred shares (see note 11).

**Offsetting**

Financial assets and liabilities are reported at their net amount in the statement of financial position if there is a legally enforceable right of setoff and there is an intention to settle by setoff. The legally enforceable right must not be contingent on future events and must be enforceable in the normal course of business and in the event of default, insolvency or bankruptcy of the company or the counterparty.

**Impairment**

(i) Trade and other receivables

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 that the loss event had a negative effect on the estimated future cash flows of that receivable that can be estimated reliably. A loss event is the inability of a debtor to pay because of its bankruptcy. 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 2013, 2014 or 2015.

(ii) Non-financial assets

Assets that are subject to depreciation / 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 the 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.

## Income taxes

Income taxes comprise current and deferred tax. Current tax and deferred tax 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 any adjustment to tax 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 the 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 organized 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
- 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, cash and cash equivalents and trade and other payables is a reasonable approximation of the fair value and therefore information about the fair values of those financial instruments has not been disclosed. The note disclosure for the fair value of a loan (financial liability) is based on level 2 measurement procedures (see note 20).

## Loss per share

Affimed presents loss per share data for its common shares. Loss per common share is calculated by dividing the loss of the period by the weighted average number of common shares outstanding during the period, adjusted for the stock split in 2014 (see note 18).

The Company has granted warrants under the Perceptive loan agreement (see note 20) and options to share-based payment programs (see note 19) which potentially have a dilutive effect. As of December 31, 2015, December 31, 2014 and December 31, 2013 no instruments actually had a dilutive effect.

### **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 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 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

Elements of consideration in collaboration and license agreements are non-refundable up-front research funding payments, technology access fees and milestone payments. Generally, the Group has continuing performance obligations and therefore up-front payments are deferred and the related revenues recognized in the period of the expected performance. Technology access fees are generally deferred and recognized over the expected term of the research service agreement on a straight line basis.

The Group estimates that the achievement of a milestone reflects a stage of completion under the terms of the agreements and recognizes revenue when a milestone is achieved. If the research service is cancelled due to technical failure, the remaining deferred revenues from upfront payments are recognized.

### **New standards and interpretations applied for the first time**

A number of amendments to standards and new or amended interpretations are effective for annual periods beginning on or before January 1, 2015, and have been applied in preparing these financial statements.

Standard/interpretation	Effective Date <sup>1</sup>
Annual Improvements to IFRSs 2010-2012 Cycle	July 1, 2014
Annual Improvements to IFRSs 2011-2013 Cycle	July 1, 2014

<sup>1</sup> Shall apply for periods beginning on or after the effective date.

None of these amendments to standards and new or amended interpretations had an effect on the consolidated financial statements of the Group.

### **New standards and interpretations not yet adopted**

The following standards, amendments to standards and interpretations are effective for annual periods beginning after December 31, 2015, and have not been applied in preparing these consolidated financial statements.

Standard/interpretation	Effective Date <sup>1</sup>
Annual Improvements to IFRSs 2012-2014 Cycle	January 1, 2016
Amendments to IAS 16, 38 Clarification of acceptable methods of depreciation and amortization	January 1, 2016
Amendments to IAS 1 Disclosure Initiative	January 1, 2016
Amendments to IAS 7 Disclosure Initiative	January 1, 2017
Amendments to IFRS 10, 12 and IAS 28 Investment Entities	January 1, 2016
Amendment to IFRS 11 Accounting for Acquisitions of Interests in Joint Operations	January 1, 2016
IFRS 15 Revenue from Contracts with Customers	January 1, 2018
IFRS 9 Financial Instruments (2014)	January 1, 2018
IFRS 16 Leases	January 1, 2019

<sup>1</sup> Shall apply for periods beginning on or after the effective date.

The Group is assessing the potential impact that IFRS 9, 15 or 16 could have on its consolidated financial statements. The other new or amended standards and interpretations are not expected to have a significant effect on the consolidated financial statements of the Group.

## **5. Segment reporting**

### **(i) Information about reportable segment**

The Group is active in the discovery, pre-clinical and clinical development of antibodies based on core technology. The activities are either conducted as own project development or for third party companies.



Management of resources and reporting to the decision maker 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 the country of domicile and other countries. 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.

	2013	2014	2015
<b>Revenues:</b>			
Germany	350	111	125
Europe	344	367	711
USA	4,393	2,904	6,725
	<u>5,087</u>	<u>3,382</u>	<u>7,562</u>
<b>Non-current assets as of December 31:</b>			
Germany		695	692
Czech Republic		351	295
		<u>1,046</u>	<u>987</u>

(iii) Major Customers

In 2013, the Group's revenue from the Amphivena collaboration agreement exceeded 10%. In 2014 and 2015, the Group's revenue with each of its two collaboration partners, Amphivena and the Leukemia and Lymphoma Society (in the following LLS), exceeded 10% (see note 6).

## 6. Revenue

### Collaboration agreement Amphivena

Affimed is party to a collaboration with Amphivena Therapeutics Inc., San Francisco, USA (in the following Amphivena) to develop a product candidate for hematologic malignancies. The collaboration consists of a series of linked transactions which in substance form a research and development collaboration. Amphivena is a structured entity with one project and uses the funding it receives from investors (which include Affimed) and Janssen Biotech Inc., Horsham, USA (in the following Janssen) to pay Affimed for its research and development services. Once approval of an investigational new drug application (IND) for the product candidate is obtained, Janssen has an option to acquire Amphivena on predetermined terms and the investors could receive further payments.

The relevant linked agreements consist of:

- a license and development agreement between Affimed and Amphivena,
- a stock purchase agreement between Amphivena, its investors (which include Affimed) for purposes of financing Amphivena, and
- a warrant agreement between Amphivena and Janssen for purposes of financing Amphivena and providing Janssen the option to acquire the results of the research and development activities through an acquisition of Amphivena following IND approval.

Pursuant to the license and development agreement between Affimed and Amphivena, Affimed grants a license to intellectual property and agreed to perform certain services for Amphivena related to the development of a product candidate for hematological malignancies. In consideration for the research and development work to be performed, Amphivena could be required to pay to Affimed service fees totaling approximately €16 million (net of Affimed's share in funding Amphivena) payable according to the achievement of milestones and phase progressions as described under the license and development agreement.

Affimed recognized revenue of €8.6 million upon achievement of three milestones consisting of the earned milestone payments of €9.0 million less Affimed's share in funding Amphivena of €0.4 million in 2013 (€4.4 million), 2014 (€1.8 million) and 2015 (€2.4 million).

After the achievement of the third milestone, the Group continues to provide research and development services to Amphivena for nonrefundable advance payments of €7.5 million in the aggregate, payable in three installments (€1.3 million, €4.2 million and €2.0 million). Revenue for these research and development services is recognized, net of Affimed's share in funding Amphivena of €0.3 million, over the service performance period. The first two installments of €5.2 million (€5.5 million, net of Affimed's share of €0.3 million) were received in 2015. The Company recognized €2.4 million as revenue for these research and development services in 2015, €2.8 million were deferred as of December 31, 2015.

Amphivena has obtained funding solely by issuing preferred stock to investors and under the warrant agreement with Janssen. Investors provide financing in exchange for preferred stock issued by Amphivena under the terms of a stock purchase agreement. Affimed participated in the financing of Amphivena with an amount of €0.7 million.

#### **Collaboration agreement The Leukemia & Lymphoma Society (LLS)**

Affimed is party to a collaboration with LLS to fund the development of a specific TandAb. Under the terms of the agreement, LLS has agreed to contribute up to \$4.4 million contingent upon the achievement of certain milestones.

In the event that the research and development is successful, Affimed must proceed with commercialization of the licensed product. If Affimed decides for business reasons not to continue the commercialization, Affimed must at its option either repay the amount funded or grant a license to LLS to enable LLS to continue with the development program. In addition, LLS is entitled to receive royalties from Affimed based on the Group's future revenue from any licensed product, with the amount of royalties not to exceed three times the amount funded.

The Company achieved several milestones and recognized revenue for related payments of €1.1 million in 2014 and €1.6 million in 2015 for research and development services.

## Research service agreements

AbCheck has entered into certain research service agreements. These research service agreements provide for non-refundable upfront technology access research funding or capacity reservation fees and milestone payments. The Group recognized revenue of €344 in 2013, €478 in 2014 and €1,126 in 2015.

## 7. Other income and expenses - net

Other income and expense, net mainly comprises income from government grants for research and development projects of €716 (2014: €381, 2013: €533). In 2013, losses from the disposal of assets of €33 were included.

## 8. Research and development expenses

The following table shows the different types of expenses allocated to research and development costs:

	2013	2014	2015
Third-party services	5,680	5,558	15,386
Personnel expenses	5,273	292	3,637
Legal, consulting and patent expenses	1,405	1,549	902
Cost of Materials	709	844	902
Amortisation and depreciation	427	428	308
Operating lease expenses	258	243	267
Other expenses	602	681	606
	<u>14,354</u>	<u>9,595</u>	<u>22,008</u>

In 2014, personnel expenses and Legal, consulting and patent expenses include gains for share based payments resulting from the decrease in the carrying amount of the liability for share-based payments prior to the corporate reorganization (see note 19).

## 9. General and administrative expenses

The following table shows the different types of expenses allocated to general and administrative costs:

	2013	2014	2015
Personnel expenses	5,165	-2,836	3,658
Legal, consulting and audit fees	1,445	4,391	2,468
Operating lease expenses	71	81	89
Other expenses	365	710	1,333
	<u>7,046</u>	<u>2,346</u>	<u>7,548</u>

In 2014, personnel expenses and Legal, consulting and audit fees include gains for share based payments resulting from the decrease in the carrying amount of the liability for share-based payments

due to the corporate reorganization (see note 19).

## 10. Employee benefits

The following table shows the items of employee benefits:

	2013	2014	2015
Wages and salaries	2,490	3,176	5,066
Social security costs	430	470	583
	<u>2,920</u>	<u>3,646</u>	<u>5,649</u>

The employer's contributions to pension insurance plans of €269 (2014: €242, 2013: €216) are classified as payments under a defined contribution plan, and are recognized in full as an expense accordingly.

## 11. Finance income and finance costs

	2013	2014	2015
Gain from exchange of Preferred Shares of Affimed AG into Common Shares of Affimed N.V. (see note 2)	0	4,835	0
Changes in fair value of derivative conversion feature	-5,553	6,094	0
Interest Preferred Shares	-4,478	-3,617	0
Interest Convertible Loan	-359	-402	0
Interest Perceptive Loan Agreement (see note 20)	0	-260	-703
Foreign exchange differences	-11	1,106	1,808
Other finance income/finance costs	4	-3	-1
Finance income/costs - net	<u>-10,397</u>	<u>7,753</u>	<u>1,104</u>

On June 23, 2014, the investors and the Company agreed to a conversion of the loan granted by several shareholders as of June 28, 2013 into Series E preferred shares of Affimed Therapeutics AG. Subsequently, all preferred shares were exchanged for newly issued common shares of Affimed N.V. (see note 2). Through the date of conversion, interest costs of €402 have been recognized in 2014 (2013: €359). A re-measurement gain from changes in the fair value of the derivative conversion feature of €6,094 was recognized in 2014 (2013: loss of €5,553).

**12. Income taxes**

The Company did not incur any material income tax in the periods presented. As of December 31, 2015 deferred tax liabilities from temporary differences result mainly from borrowings (€142) and other assets (€45). Deferred tax assets from differences resulting from trade and other receivables (€338), intangible assets (€44) and trade and other payables (€15) have not been recognized as deferred tax assets as no sufficient future taxable profits or offsetting deferred tax liabilities are available. A reconciliation between actual income taxes and the expected tax benefit from the loss before tax multiplied by the Company's applicable tax rate is presented below:

	2013	2014	2015
Loss before tax	-26,100	-425	-20,239
Income tax benefit at tax rate of 29.825%	7,784	127	6,036
Adjustments due to impairment of deferred tax assets	-7,818	2,787	-6,251
Change in permanent differences	0	-2,837	199
Adjustments for local tax rates	-9	119	18
Non deductible expenses	0	0	163
Other	44	-30	-165
Income taxes	1	166	0

In Germany, Affimed has tax losses carried forward of €89.2 million (2014: €68.2 million) for corporate income tax purposes and of €89.0 million (2014: €68.0 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 were mitigated through Economic Growth Acceleration Act (Wachstumsbeschleunigungsgesetz). According to the provisions of this act unused tax losses of a corporation as at 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 Company. 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.

In the Czech Republic, AbCheck incurred tax losses of €0.3 million (2014: €0.6 million) available within five years from the year incurred for offsetting against future taxable profits for which no deferred tax assets has been recognized.

**13. Intangible assets**

The following table shows the reconciliation of intangible assets for the year 2014:

	Technology licenses	Office software	Total
Cost as of January 1	342	301	643
Additions	19	27	46
Reallocation	200	-200	0
Cost as of December 31	561	128	689
Accumulated depreciation as of January 1	222	263	485
Reallocation	195	-195	0
Additions	115	17	132
Accumulated depreciation as of December 31	532	85	617
Carrying amount as of January 1	120	38	158
Carrying amount as of December 31	29	43	72

The following table shows the reconciliation of intangible assets for the year 2015:

	Technology licenses	Office software	Total
Cost as of January 1	561	128	689
Additions	0	28	28
Disposals	-183	-48	-231
Cost as of December 31	378	108	486
Accumulated depreciation as of January 1	532	85	617
Additions	10	18	28
Disposals	-183	-48	-231
Accumulated depreciation as of December 31	359	55	414
Carrying amount as of January 1	29	43	72
Carrying amount as of December 31	19	53	72

#### 14. Leasehold improvements and equipment

The following table shows the reconciliation of tangible assets for the year 2014:

	Leasehold improvements	Laboratory equipment, furniture and fixtures	Total
Cost as of January 1	183	2,502	2,685
Additions	2	258	260
Disposals	0	-55	-55
Cost as of December 31	185	2,705	2,890
Accumulated depreciation as of January 1	181	1,470	1,651
Additions	1	309	310
Disposals	0	-45	-45
Accumulated depreciation as of December 31	182	1,734	1,916
Carrying amount as of January 1	2	1,032	1,034
Carrying amount as of December 31	3	971	974

The following table shows the reconciliation of tangible assets for the year 2015:

	Leasehold improvements	Laboratory equipment, furniture and fixtures	Total
Cost as of January 1	185	2,705	2,890
Additions	23	226	249
Disposals	-179	-609	-788
Cost as of December 31	29	2,322	2,351
Accumulated depreciation as of January 1	182	1,734	1,916
Additions	4	304	308
Disposals	-179	-609	-788
Accumulated depreciation as of December 31	7	1,429	1,436
Carrying amount as of January 1	3	971	974
Carrying amount as of December 31	22	893	915

## 15. Inventories

Inventories comprise laboratory materials and supplies of €228 (2014: €199). No impairment was recognized. Total consumption of inventories recognized in profit or loss amounts to €906 (2014: €900, 2013: €731).

## 16. Trade and other receivables

The trade receivables as at December 31, 2015 of €105 (2014: €5) are all due in the short-term, do not bear interest and are neither overdue nor impaired. Other receivables are all due short-term and mainly comprise receivables for research and development grants and other government subsidies of €68 (2014: €114) and value-added tax receivables of €607 (2014: €697).

## 17. Other assets

Other assets of €452 comprise deferred expenses related to short-term research projects of €300 and a prepayment of €152 related to probable future equity transactions based on the shelf registration filing (see note 18).

## 18. Equity

At December 31, 2015 the share capital of €333 (2014: €240) is divided into 33,259,404 (2014: 23,984,168) common shares with a par value of €0.01.

As of September 17, 2014, upon consummation of the corporate reorganization, all common and preferred shares in Affimed Therapeutics AG were exchanged for 15,984,168 common shares of Affimed (see note 2). In addition, in the initial public offering, the Company issued an aggregate of 8,000,000 common shares at a price of \$7.00 per share. In the offering, capital reserves of €37,871 were recognized net of issuing costs of €5,342.

The exchange of 37,935 common shares of Affimed Therapeutics AG for 286,160 shares of Affimed N.V. on a 7.54-for-one basis was retrospectively accounted as a stock split. The exchange of the preferred shares of Affimed Therapeutics AG did not represent a stock split as the preferred shares did not contain a conversion right into common shares.

On May 12, 2015, the Company issued 5,750,000 common shares at a public offering at a price of \$7.15 per common share. After deducting the offering expenses of €3,091, equity increased by the net proceeds of the public offering of €33,490. In October 2015, an existing shareholder purchased 3,325,236 common shares at \$6.55 per share in a private placement, leading to an equity increase of €19,064, net of related expenses of €25.

According to the articles of association of Affimed N.V., up to 55,000,000 common shares and 55,000,000 preferred shares with a par value of €0.01 are authorized to be issued. As of December 31, 2015, 33,259,404 common shares have been issued and are outstanding. Preferred shareholders are



entitled to receive a fixed dividend yield prior to common shareholders, unpaid preferred dividends accumulate. As of December 31, 2015 no preferred shares have been issued.

## 19. Share based payments

Affimed Therapeutics AG had granted share-based payment awards to its managing and supervisory directors and consultants pursuant to two incentive plans: (i) the ESOP 2007 Plan granted options to acquire preferred shares at the issue price of EUR 30.89 per Series D preferred share after vesting but during the contractually agreed ten year life of the award and (ii) the carve-out plan granted the right to receive a cash payment equal to a certain percentage of the fair value of the Company contingent upon the occurrence of a defined exit event. The awards pursuant to both share-based incentive plans were accounted for as cash settled until their modification in the corporate reorganization (see note 2).

The ESOP 2007 awards entitled the beneficiary to a cash payment encompassing all preference rights and payments connected to the preferred shares, net of the strike price owed by the beneficiary. In 2013, 13,081 ESOP 2007 awards were replaced by awards under the carve-out plan. The replacement was accounted as a modification. The incremental fair value of €1,271 represents the difference between the fair value of the cancelled awards and the replacement awards.

Pursuant to the carve-out plan, awards entitled the beneficiaries to cash payments of an aggregate of 7.78% of the fair value of the Company in case of a defined exit event, including an initial public offering. The plan had a three year service condition, whereby 50% of the entitlements vested after one year, further 25% after two years and the remaining 25% after three years. In case of a successful sale of the Company during the vesting period an accelerated vesting would have applied and all entitlements vested immediately.

The ESOP 2007 and carve-out plan were both modified in the reorganization (see note 2).

In 2015, 200,000 options of the ESOP 2007 were exercised at the exercise price of \$5.29. As of December 31, 2015, 534,142 (December 31, 2014: 734,142) ESOP 2007 options were outstanding.

In the corporate reorganization on September 17, 2014, an equity-settled share based payment program was established by Affimed N.V. (ESOP 2014). Based on this program, the Company granted 555,000 awards in 2014 and 795,000 awards in 2015 to certain members of the Management Board, the Supervisory Board, consultants and employees. The awards vest in installments over three years, and the final exercise date of the options is 10 years after the grant date of the instruments.

As of December 31, 2015, 1,350,000 ESOP 2014 awards were outstanding (December 31, 2014: 555,000), 259,583 awards (December 31, 2014: 0) were vested. No awards were either forfeited or exercised. The options outstanding at December 31, 2015 had an exercise price in the range of \$5.18 to \$13.47 (2014: \$6.20 to \$6.27).

The expense of the granted options is recorded over the vesting period, starting from the service commencement date, which is generally the grant date.

In 2015, an expense of €2,220 was recognized affecting research and development expenses (€611) and general and administrative expenses (€1,609). In 2014, a net gain for share-based compensation of €4,892 was recognized affecting research and development expenses (€1,480) and general and

administrative expenses (€3,412) including a gain of €8,261 due to the re-measurement of the ESOP 2007 awards and the carve-out plan as of September 17, 2014, the modification date. In 2013, an expense of €8,054 was recognized affecting research and development expenses (€3,021) and general and administrative expenses (€5,033).

The fair value of options granted under the ESOP 2014 program was determined using the Black-Scholes valuation model. As the Company was listed on the NASDAQ the closing price of the common shares at grant date was used. Other significant inputs into the model were volatility of 65%, an expected option life of 5.9 years, annual risk-free interest rates at grant date in the range of -0.07% to 0.34% and a zero dividend yield. Expected volatility is estimated based on the observed daily share price returns of selected guideline companies measured over a historic period equal to expected life, with the peer group as insufficient trading data are available to use the share price returns of Affirmed to estimate volatility over a historic period equal to expected life. As of December 31, 2015 weighted average fair value of the options was \$4.41 (2014: \$3.63) and weighted average remaining contractual life was 9.2 years (2014: 9.7 years).

## 20. Borrowings

In July 2014, the Company entered into a credit facility agreement of \$14 million and drew an amount of \$5.5 million as of July 31, 2014. Repayment will start in April 2016 in monthly installments of \$200, with the final balance due in August 2018. Finance costs comprise interest of an annual rate of 9% plus one month LIBOR, with LIBOR deemed to equal 1% if LIBOR is less than 1%, and an arrangement fee in the amount of 2% of the facility. In addition, the Company issued 106,250 warrants to the lender. The warrants are convertible into common shares of the Company with a strike price of \$8.80. Upon initial recognition, the fair value of the warrant of €613 was recognized in equity, net of tax of €183. Fair value was determined using the Black-Scholes-Merton formula, with an expected volatility of 65% and an expected time of six years to exercise of the warrant. The contractual maturity of the warrant is ten years.

In 2015, the Company and Perceptive agreed to cancel the option to draw the outstanding facility of \$8.5 million.

The loan is collateralized by shares in AbCheck s.r.o., certain bank accounts, receivables and certain intellectual property rights with a total carrying amount of €6,202 (2014: €6,844).

The loan is measured at amortized cost using the effective interest method. Interest costs of €703 (2014: €258) and foreign exchange losses of €527 (2014: €424) have been recognized in profit or loss. As of December 31, 2015 the fair value of the liability amounts to €4,978 whereas the carrying amount is €4,576. As of December 31, 2014 the Company believes that the fair value of the liability did not differ significantly from its carrying amount (€3,895). According to the repayment schedule €1,472 (December 31, 2014: €0) were classified as current liabilities.

## 21. Trade and other payables

Trade and other payables comprise trade payables of €3,743 (2014: €3,396) and are normally settled within 30 days or at a separate settlement date which was agreed between the parties. Other payables mainly comprise payroll and employee related liabilities for withholding taxes and social security

contributions of €444 (2014: €281) and payables due to employees for outstanding bonus, holidays and other accruals. Other payables are normally settled within 30 days.

## 22. Loss per share

Loss per common share is calculated by dividing the loss of the period by the weighted average number of common shares outstanding during the period, adjusted for reorganization of the Company (see note 2).

	2013	2014	2015
Net loss	(26,099)	(259)	(20,239)
Weighted number of common shares outstanding	14,803,450	17,632,825	28,477,438
Loss per share in € per share	(1.76)	(0.01)	(0.71)

No instruments had a dilutive effect.

## 23. Operating leases and other commitments and contingencies

### (i) Lease and other commitments

The Group has entered into rental agreements for premises as well as into leases for vehicles and the use of licenses. These contracts have an average life of between one and four years with renewal options included in some contracts. There are no restrictions placed upon the lessee by entering into these leases. In 2015, lease expenses of €356 and license fees of €278 have been recognized in consolidated statement of comprehensive income (2014: €324 and €248; 2013: €328 and €260).

Future minimum lease payment obligations under non-cancellable operating leases as of the reporting date are as follows:

	2014	2015
Within one year	664	642
Between one and five years	561	990
More than five years	42	0
	<u>1,267</u>	<u>1,632</u>

(ii) 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

(i) Shareholders

As of December 31, 2015 one shareholder holds more than 20% of the voting rights (2014 and 2013 two shareholders).

(ii) Transactions with key management personnel

The compensation of managing directors and other key management personnel comprised of the following:

	2013	2014	2015
Short-term employee benefits	837	911	1,633
Share-based payments	<u>5,367</u>	<u>-3,253</u>	<u>1,474</u>
	<u>6,204</u>	<u>-2,342</u>	<u>3,107</u>

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.

Compensation for other key management personnel comprises fixed and variable components and share-based payment awards.

Affimed N.V.  
Notes to the consolidated financial statements  
(in € thousand)

The supervisory directors of Affimed N.V., appointed as of September 12, 2014, received compensation for their services on the supervisory board of €296 (2014: €85), the supervisory directors of Affimed Therapeutics AG, the predecessor of Affimed N.V., did not receive compensation for their services on the supervisory board. In 2015, the Group recognized expenses for share-based payments for board members of €478 (2014: €727, 2013: €245).

Selected managing directors and supervisory directors entered into service and consulting agreements with the Company:

Dr. Florian Fischer is founder and Chief Executive Officer of MedVenture Partners, a Munich-based corporate finance and strategy advisory company focusing on the life sciences and health care industry. MedVenture Partners rendered services for a consideration of €129 in 2014 and €30 in 2013. The contract with MedVenture Partners was terminated following the IPO in 2014.

Dr. Adolf Hoess received compensation for consulting services of €163 in 2014 and €314 in 2013. The consulting contract with Dr. Adolf Hoess was terminated following the IPO in 2014.

Dr. Thomas Hecht is Head of Hecht Healthcare Consulting (HHC) in Küsnacht, Switzerland, a biopharmaceutical consulting company. In 2013, he rendered services amounting to €65, in 2014 he received €49.

Dr. Richard B. Stead is Founder and Principal of BioPharma Consulting Services LLC, where he is involved in the development of a number of oncology products including different strategies for cancer immunotherapy. In 2013, he rendered services amounting to €40, in 2014, he received €25.

Dr. Ulrich Grau is a significant shareholder and Chairman of the Board of Directors of i-novion Inc., which was engaged by the Company to conduct preclinical services. In 2015, i-novion Inc. received related payments of €138.

The following table provides the total amounts of outstanding balances related to key management personnel:

	Outstanding balances	
	December 31, 2014	December 31, 2015
Thomas Hecht	19	19
Richard Stead	6	6
Berndt Modig	7	9
Ferdinand Verdonck	7	11
Eugene Zhukovsky	16	0
Ulrich Grau	0	13

## 25. Financial risk management

### (i) Financial risk management objectives and policies

The Group's principal financial instruments comprise short-term deposits at commercial banks with a maturity on inception of three months or less 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 main risks arising from the Group's financial instruments are credit risk and liquidity risk. The measures taken by management to manage each of these risks are summarized below.

### (ii) Credit risk

The Company's financial assets comprise to a large extent cash and cash equivalents. In addition financial assets include trade and other receivables. The total carrying amount of cash and cash equivalents (€76.7 million, 2014: €39.7 million) and trade and other receivables (€0.9 million, 2014: €0.9 million) represents the maximum credit exposure of €77.6 million (2014: €40.7 million).

The cash and cash equivalents are held with banks, which are rated BBB- to AA- based on Standard & Poor's and Moody's.

### (iii) Interest rate risk

The group's interest rate risk arises from cash accounts and long-term borrowings at variable rates.

Affimed entered into the Perceptive loan agreement pursuant to which it borrowed \$5.5 million with a variable interest rate of an annual rate of 9% plus one-month LIBOR, with LIBOR deemed to equal 1% if LIBOR is less than 1%. The group does not expect the LIBOR to exceed the floor of 1% within the foreseeable future, and considers the interest risk to be low.

Bank accounts of €38.5 million (2014: €7.0 million) are exposed to interest rate risk. A shift in interest rates (increase or decrease) would not have a material impact on the loss of the group.

### (iv) 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 exposed to Czech Koruna (CZK) and US Dollars (USD). The net exposure as of December 31, 2015 was €27,423 (2014: €5,983) and mainly relates to US Dollars.

In 2015, if the Euro had weakened/strengthened by 10% against the US dollar with all other variables held constant, the loss would have been €2,794 (2014: €611) higher/lower, mainly as a result of foreign exchange gains/losses on translation 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 2015 than in 2014 because of the

increased volume of US dollar-denominated transactions.

The following significant exchange rates have been applied during the year:

	2013 CZK or USD/EUR	2014 CZK or USD/EUR	2015 CZK or USD/EUR
CZK - Average Rate	0.03850	0.03632	0.03666
CZK - Spot rate	0.03640	0.03606	0.03701
USD - Average Rate	0.75340	0.75273	0.90190
USD - Spot rate	0.72633	0.82366	0.91853

(v) 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 2014 and 2015, Affimed raised significant funding that it estimates will enable the group to fund operating expenses and capital expenditure requirements until Q1 2018:

In 2015, the issue of new common shares and the exercise of stock options resulted in net proceeds of €53,498 (see note 18).

The group expects to require additional funding to complete the development of the existing product candidates. In addition, the group expects to require additional capital to commercialize the products if regulatory approval is received.

In 2015, Affimed has filed a "shelf registration statement" with the SEC in order to offer and sell securities to the public in multiple, future offerings.

(vi) 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.



Affimed GmbH - Im Neuenheimer Feld 582 - 69120 Heidelberg

Perceptive Credit Opportunities Fund, LP  
 Attn.: Joseph Edelman  
 499 Park Avenue, 25th Floor  
 New York, New York 10022  
 United States of America

April 29, 2015

**Affimed Loan Agreement: Amendment to include Affimed Inc. as member of the Group**

Dear Mr. Edelman,

As discussed by email between Sandeep and me, Affimed GmbH intends to grant upfront financing (contribution to equity) to Affimed Inc., c/o Morris & Morris, P.C., 32 Kearney Road, Needham Heights, MA 02494, a wholly owned subsidiary of Affimed GmbH, in an amount of USD 100,000. We agreed that Affimed GmbH may provide the aforementioned funding to Affimed Inc., if the Term Facility Agreement between Affimed GmbH and Perceptive Credit Opportunities Fund, LP is amended as to also include Affimed Inc. as a member of the Group.

We hereby agree that Affimed Inc. shall be considered a member of the Group under the Term Facility Agreement dated July 28, 2014 as defined in Section 1.1 thereof as well as a member of the Group under the Global Assignment Agreement dated July 28, 2014 as defined in Section 1.1 thereof, provided however that any additional funding of Affimed Inc. by another member of the Group requires prior approval of the Lender.

As a sign of your agreement, please return a duly executed copy of this letter to us by either fax to +49 6221 65307 77 or by overnight courier.

Affimed GmbH

/s/ Florian Fischer

Florian Fischer  
 Chief Financial Officer

/s/ Michael Wolf

Michael Wolf  
 Head of Finance

**Agreed:**

Perceptive Credit Opportunities Fund, LP  
 By: Perceptive Credit Opportunities GP, LLC, its general partner

/s/ Joseph Edelman

Joseph Edelman  
 Chief Executive Officer & Portfolio Manager  
 Date: April 30, 2015

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 Sitz der Gesellschaft: Heidelberg  
 Registergericht: Amtsgericht Mannheim  
 HRB 721206 – VAT.Nr.: DE 206700144

Geschäftsführer:  
 Dr. Adi Hoess  
 Dr. Florian Fischer  
 Dr. Jens-Peter Marschner  
 Dr. Martin Treder



**Second Amendment Agreement**  
**relating to the Facility Agreement dated July 28, 2014**

between

**Affimed GmbH**

as Borrower

and

**Affimed N.V.**

as Dutch Guarantor

and

**Perceptive Credit Opportunities Fund, LP**

as Lender

**MORRISON**  
**FOERSTER**

This AMENDMENT AGREEMENT (the “**Agreement**”) is made between:

(1) **Affimed GmbH** (former Affimed Therapeutics AG), a company incorporated as a limited liability corporation (*Gesellschaft mit beschränkter Haftung*) incorporated under the laws of the Federal Republic of Germany, registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mannheim, Germany under HRB 721206 and having its business address at Im Neuenheimer Feld 582, 69120 Heidelberg, Germany,

- hereinafter referred to as “**Borrower**” -

(2) **Affimed N.V.**, a company incorporated as a stock corporation (*naamloze vennootschap*) incorporated under the laws of the Netherlands, registered with the commercial register of the Netherlands under 60673389 and having its business address at Im Neuenheimer Feld 582, 69120 Heidelberg, Germany,

- hereinafter referred to as “**Dutch Guarantor**” -

(3) **Perceptive Credit Opportunities Fund, LP**, a limited partnership, established and validly existing under the laws of Delaware, United States, with its business address at 499 Park Avenue, 25th Floor, New York, New York 10022,

- hereinafter referred to as “**Lender**” -

- The Borrower, the Dutch Guarantor and the Lender are together referred to as the “**Parties**”, each as a “**Party**” -

## Preamble

- (A) On July 28, 2014 the Borrower and PCOF 1, LLP, a limited liability company governed by the laws of Delaware, having its business address at 499 Park Avenue, 25th Floor, New York, New York 10022 (“**Original Lender**”) as lender entered into a facility agreement (“**Facility Agreement**”), a U.S. IP Security Agreement (“**U.S. Security Agreement**”), a Global Assignment Agreement and several other security agreements (U.S. Security Agreement, Global Assignment Agreement and the other security agreements together the “**Security Agreements**”; the Facility Agreement and the Security Agreements also jointly referred to as “**Finance Documents**”) (Notarial deed dated July 28, 2014 with notarial deed number 2569V/2014 of the notary Dr. Hans-Joachim Vollrath) by which the Original Lender provided to the Borrower a facility in the amount of USD 5,500,000.00 (“**Facility A**”) and a facility in the amount of USD 8,500,000.00 (“**Facility B**”).
- (B) On September 19, 2014 the Dutch Guarantor acceded to the Facility Agreement as a guarantor.
- (C) On October 6, 2014 the Dutch Guarantor and the Original Lender entered into a warrant agreement in regard to 106,250 shares in the Dutch Guarantor in favor of the Original Lender (“**Dutch Warrant**”).
- (D) On December 4, 2014 the Original Lender, the Borrower and the Dutch Guarantor entered into several transfer agreements (Notarial deed dated December 4, 2014 with notarial deed number 4058V/14 of the notary Dr. Hans-Joachim Vollrath) by which the Original Lender transferred the Facility Agreement and the Security Agreements by way of assumption of contracts (*Vertragsübernahme*) to the Lender. At the same date the Original Lender transferred, by Deed of Transfer dated December 12, 2014, the Dutch Warrant to the Lender.
- (E) In April 2015 the Borrower established Affimed Inc., a stock corporation under US law (“**Affimed Inc.**”). On April 29, 2015 the Lender and the Borrower entered into an amendment agreement to the Facility Agreement by which the Lender approved a financing of Affimed Inc. by the Borrower up to an amount of USD 100,000.
- (F) In 2014 and 2015 Borrower filed new patent applications with the European Patent Office and the USPTO indicated as “Cross-Reactive CD3”, “Trispecifics” and “Combination AFM13 and CPI” (described in Annex F) (“**New Patents**”). Upon request of the Borrower, the Lender intends to waive the Borrowers obligation under the Finance Documents, as defined in the Facility Agreement, to pledge the New Patents to the Lender.
- (G) The Borrower’s obligation under the Finance Documents to pledge, assign or otherwise provide security regarding the Borrower’s future intellectual property rights shall be amended as follows: With regard to the Borrower’s intellectual property rights which will be applied for, filed for registration or otherwise come into existence after the date hereof (“**Future IP Rights**”), the Borrower’s obligation under the Finance Documents shall be subject to the Lender’s request, and if such request is not made, be deemed to have been waived by the Lender.

- (H) Furthermore, the Parties intend to agree that the Availability Period, as defined in the Facility Agreement, in relation to Facility B shall lapse on June 30, 2015.
- (I) Additionally, the Certificate of the Dutch Warrant, currently naming the Original Lender as “Holder”, shall be exchanged against an identical warrant certificate naming the Lender as “Holder”.

NOW, THEREFORE, the Parties agree as follows:

**1. AMENDMENT TO THE FACILITY AGREEMENT**

The Facility Agreement shall hereby be amended and restated as follows:

- 1.1 In Section 1, Clause 1.1 Definitions, page 4, the following definition of the term Availability Period:

**“Availability Period” means:**

- (a) *in relation to Facility A, the period from and including the date of this Agreement to and including December 31, 2015; and*
- (b) *in relation to Facility B, the period from and including November 1, 2014 to and including December 31, 2015.”*

shall be replaced by the following wording:

**“Availability Period” means:**

- (c) *in relation to Facility A, the period from and including the date of this Agreement to and including December 31, 2015; and*
- (d) *in relation to Facility B, the period from and including November 1, 2014 to and including June 30, 2015.”*

- 1.2 Section 5, Clause 10.1.1, page 25 with the wording

*“10.1.1 Beginning on November 1, 2014, the Borrower shall pay to the Lender a fee of one per cent (1%) per annum on that Lender’s Available Commitment. For the avoidance of doubt, no commitment fee shall apply after December 31, 2015.”*

shall be replaced by the following wording:

*“10.1.1 Beginning on November 1, 2014, the Borrower shall pay to the Lender a fee of one per cent (1%) per annum on that Lender’s Available Commitment. For the avoidance of doubt, no commitment fee shall apply after June 30, 2015.”*

- 1.3 The provisions of the Facility Agreement shall, save as amended by this Agreement, continue in full force and effect.

## 2. WAIVER REGARDING NEW PATENTS

2.1 The Lender hereby waives any pledge, assignment or similar security and any obligation of the Borrower under the Finance Documents to pledge, assign or grant any other security regarding the New Patents to the Lender as collateral. The Borrower accepts the aforementioned waiver. All other obligations thereunder, especially the restriction not to pledge intellectual property rights, including the New Patents, to a third party, remain in full force and effect and shall not be waived hereby.

2.1 The Borrower's obligation under the Finance Documents to pledge, assign or otherwise provide security regarding a Future IP Right as well as any pledge, assignment or other security regarding the respective Future IP Right shall be deemed to be waived by the Lender if:

2.1.1 The Borrower has notified the Lender of such Future IP Right without undue delay after such individual Future IP Right has been applied for, filed for registration or otherwise come into existence ("**Notification**"); and

2.1.2 The Lender has not requested the Borrower to pledge, assign or otherwise provide security regarding such notified Future IP Right within ten Business Days (as defined in the Facility Agreement) after such Notification has been received by the Lender.

The aforementioned waiver shall only apply to the specific Future IP Right as listed and provided with a reasonable satisfactory description in the Notification. For the avoidance of doubt, in case the Borrower does not, or does not correctly notify the Lender of a Future IP Right, the Borrower's obligation to pledge, assign or otherwise provide security regarding the same continues to exist.

## 3. UNDERTAKING

3.1 The Dutch Guarantor shall ensure that within four (4) weeks after signing of this Agreement, the Lender receives, in exchange for the current certificate of the Dutch Warrant, a warrant certificate with regard to 106,250 shares in the Dutch Guarantor ("**New Warrant Certificate**"), which is identical to the current certificate of the Dutch Warrant, except that instead of the Original Lender the Lender is named as "Holder" in such certificate.

3.2 The Dutch Guarantor shall, to the reasonable satisfaction of the Lender, provide the New Warrant Certificate pursuant to 3.1. The Dutch Guarantor has provided a written statement from an independent legal counsel of the Dutch Guarantor confirming that the Legal Opinion dated October 7, 2014, also applies to the New Warrant Certificate and consequently, can still be relied upon by the Lender.

## 4. TRANSACTION EXPENSES

The Borrower shall bear all costs and expenses (including legal fees) incurred in connection with the negotiation, preparation, and execution of this Agreement and any other documents referred to in this Agreement.

## 5. NOTICES AND COMMUNICATION

Any communication to be made under or in connection with this Agreement shall be made in writing and, unless otherwise stated, may be made by fax or overnight courier to the following addresses:

if directed to the Borrower, to:

Affimed GmbH  
Technologiepark, Im Neuenheimer Feld 582  
69120 Heidelberg, Germany  
Attn: Dr. Florian Fischer  
Fax: +49 6221 65307 77  
Email: f.fischer@affimed.com

with a copy to

CMS Hasche Sigle  
Partnerschaft von Rechtsanwälten und Steuerberatern mbB  
Nymphenburger Straße 12  
80335 Munich, Germany  
Attn: Stefan-Ulrich Müller  
Fax: +49 89 23807 40667  
Email: Stefan-Ulrich.Mueller@cmshs.com

if directed to the Dutch Guarantor, to:

Affimed N.V.

Technologiepark, Im Neuenheimer Feld 582  
69120 Heidelberg, Germany  
Attn: Dr. Florian Fischer  
Fax: +49 6221 65307 77  
Email: f.fischer@affimed.com

with a copy to

CMS Hasche Sigle  
Partnerschaft von Rechtsanwälten und Steuerberatern mbB  
Nymphenburger Straße 12  
80335 Munich, Germany  
Attn: Stefan-Ulrich Müller  
Fax: +49 89 23807 40667  
Email: Stefan-Ulrich.Mueller@cms-hs.com

if directed to the Lender, to:

Perceptive Advisors LLC  
499 Park Avenue, 25th Floor  
New York, New York 10022  
United States of America

Attn: Sandeep Dixit  
Email: Sandeep@perceptivelife.com

with a copy to:

Morrison & Foerster LLP  
Potsdamer Platz 1  
10785 Berlin, Germany  
Attn: Jörg Meißner  
Fax: +49 30 726 221 130  
Email: jmeissner@mfo.com

## **6. MISCELLANEOUS**

- 6.1 If provisions in this Agreement include English terms after which German terms or Dutch terms have been inserted in brackets and/or italics, the respective German terms or Dutch term alone and not the English terms shall be decisive for the interpretation of the respective provisions.
- 6.2 Any amendment or supplement to or modification of this Agreement, including this provision, shall be valid only if made in writing, except where a stricter form (e.g., notarization) is required under applicable mandatory law.
- 6.3 Should any provision of this Agreement be or become, or be deemed to be or become, invalid or unenforceable as a whole or in part, the validity and enforceability of the remaining provisions shall not be affected thereby. Any such invalid or unenforceable provision shall be replaced by such valid and enforceable provision as comes closest to the economic intent and purpose of such invalid or unenforceable provision. The same shall apply in the event that this Agreement contains any gaps (*Vertragslücken*).
- 6.4 This Agreement is governed by the laws of the Federal Republic of Germany. Any non-contractual rights and obligations arising out of or in connection with this Agreement shall also be governed by the laws of the Federal Republic of Germany.
- 6.5 The courts of Frankfurt am Main have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute regarding the existence, validity or termination of this Agreement).

[Signature page follows the next page]

**Affimed GmbH**

in its capacity as Borrower

Place/Date: Heidelberg, August 14, 2015

Place/Date: Heidelberg, August 14, 2015

/s/ Dr. Adi Hoess

Name: Dr. Adi Hoess  
Function: Chief Executive Officer

/s/ Dr. Florian Fischer

Name: Dr. Florian Fischer  
Function: Chief Financial Officer

**Affimed N.V.**

in its capacity as Dutch Guarantor

Place/Date: Heidelberg, August 14, 2015

Place/Date: Heidelberg, August 14, 2015

/s/ Dr. Adi Hoess

Name: Dr. Adi Hoess  
Function: Chief Executive Officer

/s/ Dr. Florian Fischer

Name: Dr. Florian Fischer  
Function: Chief Financial Officer

**Perceptive Credit Opportunities Fund, LP**

in its capacity as Lender

by: Perceptive Credit Opportunities GP, LLC, its general partner

Place/Date: New York, August 14, 2015

/s/ Joseph Edelman

Name: Joseph Edelman  
Function: Chief Executive Officer & Portfolio Manager





Affimed GmbH Affimed N.V. Im Neuenheimer Feld 582 69120 Heidelberg

Perceptive Credit Opportunities Fund, LP  
 Mr. Edelman  
 51 Astor Place  
 10<sup>th</sup> Floor  
 New York  
 New York 10003  
 USA

March 29, 2016

**Term Facility Agreement dated July 24, 2014  
 Waiver regarding a Development Milestone (Clause 19.2)**

Dear Mr. Edelman,

We are writing to you on behalf of Affimed GmbH and on behalf of Affimed N.V. As discussed with Sam Chawla and Sandeep Dixit, we are contemplating to discuss with you the structure and certain terms of the Term Facility Agreement between Affimed GmbH (formerly Affimed Therapeutics AG, the "**Company**") as Borrower, Affimed N.V. as Guarantor and funds managed by Perceptive Advisors LLC – currently Perceptive Credit Opportunities Fund, LP and PCOF Phoenix II Fund, LP – as Lenders, dated July 24, 2014 (as amended from time to time, the "**Agreement**"). In connection therewith and in order to better reflect the Company's current development strategy, the Parties might also agree on development milestones other or different than those currently set-out in Schedule 6 to the Agreement.

To allow for sufficient time for the above mentioned discussions, the Lender hereby agrees to waive, up and until September 30, 2016, any rights it may have under Section 21.13 (Events of Default, Other obligations) of the Agreement in connection with 19.2 (Development of Milestones) and Schedule 6, No. 2 of the Agreement. For the avoidance of doubt, all other rights and obligations of the Parties under the Agreement remain unaffected, in particular, but not limited to, the Lender's rights under Section 21.13 (*Events of Default, Other obligations*) in case of any non-compliance with any provision of the Finance Documents other than 19.2 (*Development of Milestones*), Schedule 6, No. 2.

Terms defined in the Agreement have the same meaning in this letter, unless otherwise defined herein. This letter is governed by German law.

**Affimed GmbH**  
**Affimed N.V.**  
 Technologiepark  
 Im Neuenheimer Feld 582  
 69120 Heidelberg  
 Germany

**Phone:** +49 6221 65307 0  
**Fax:** +49 6221 65307 49  
[www.affimed.com](http://www.affimed.com)  
 E-Mail: [info@affimed.com](mailto:info@affimed.com)

Bankverbindung: Deutsche Bank  
 IBAN DE 5867 2700 0300 1408 0600  
 BIC DEUTDESM672  
 Sitz der Gesellschaft: Heidelberg  
 Registergericht: Amtsgericht Mannheim  
 HRB 721206 – VAT.Nr.: DE 206700144

Geschäftsführer der Affimed GmbH:  
 Dr. Adi Hoess  
 Dr. Florian Fischer  
 Dr. Jens-Peter Marschner  
 Dr. Martin Treder  
 Dr. Jörg Windisch



Please return countersigned copies of this letter to Affimed GmbH and to Affimed N.V. at your earliest convenience.

Kind regards

On behalf of Affimed GmbH:

March 29, 2016  
Date

/s/ Adi Hoess  
Dr. Adi Hoess  
CEO

/s/ Florian Fischer  
Dr. Florian Fischer  
CFO

On behalf of Affimed N.V.

March 29, 2016  
Date

/s/ Adi Hoess  
Dr. Adi Hoess  
CEO

/s/ Florian Fischer  
Dr. Florian Fischer  
CFO

**Affimed GmbH**  
**Affimed N.V.**  
Technologiepark  
Im Neuenheimer Feld 582  
69120 Heidelberg  
Germany

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Sitz der Gesellschaft: Heidelberg  
Registergericht: Amtsgericht Mannheim  
HRB 721206 – VAT.Nr.: DE 206700144

Geschäftsführer der Affimed GmbH:  
Dr. Adi Hoess  
Dr. Florian Fischer  
Dr. Jens-Peter Marschner  
Dr. Martin Treder  
Dr. Jörg Windisch



Accepted and Agreed

On behalf of Perceptive Credit Opportunities Fund, LP  
And PCOF Phoenix II Fund, LP

March 29, 2016  
Date

/s/ Joseph Edelman

---

Joseph Edelman

**Affimed GmbH**  
**Affimed N.V.**  
Technologiepark  
Im Neuenheimer Feld 582  
69120 Heidelberg  
Germany

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Geschäftsführer der Affimed GmbH:  
Dr. Adi Hoess  
Dr. Florian Fischer  
Dr. Jens-Peter Marschner  
Dr. Martin Treder  
Dr. Jörg Windisch

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## 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(s) 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(s) 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 30, 2016

/s/ Adi Hoess

Adi Hoess  
Chief Executive Officer

---

## CERTIFICATION

I, Florian Fischer, 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(s) 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(s) 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 30, 2016

/s/ Florian Fischer

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Florian Fischer  
Chief Financial 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, 2015 (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, Chief 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 30, 2016

/s/ Adi Hoess

\_\_\_\_\_  
Name: Adi Hoess

Chief 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, 2015 (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.

Florian Fischer, Chief Financial 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 30, 2016

/s/ Florian Fischer

\_\_\_\_\_  
Name: Florian Fischer  
Chief Financial Officer

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in Registration Statement No. 333-198812 on Form S-8 and No. 333-207235 on Form F-3 of Affimed N.V. of our report dated March 16, 2016, with respect to the consolidated statement of financial position of Affimed N.V. as of December 31, 2015 and December 31, 2014, and the related consolidated statements of comprehensive loss, cash flows and changes in equity for each of the years in the threeyear period ended December 31, 2015, which report appears in the Annual Report on Form 20-F of Affimed N.V for the year ended December 31, 2015.

/s/ KPMG AG Wirtschaftsprüfungsgesellschaft

Leipzig, Germany  
March 29, 2016

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