## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2016

OR

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

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

Commission file number: 001-37471

# PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation or organization)

255 State Street, 9 th Floor Boston, MA United States

(Address of principal executive offices)

02109 (Zip Code)

EIN 30-0784346

(I.R.S. Employer Identification No.)

Registrant's telephone number, including area code

857-246-8998

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

Title of each class Common Stock, par value \$0.01 per share Name of each exchange on which registered The NASDAQ Stock Market LLC

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

None (Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗆 No 🗵

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  $\Box$  No  $\boxtimes$ 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  $\boxtimes$  No  $\Box$ 

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  $\boxtimes$  No  $\square$ 

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.  $\Box$ 

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

Large accelerated filer  $\Box$ 

Non-accelerated filer [Do not check if a smaller reporting company]

Smaller reporting company  $\square$ 

Accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗆 No 🗵

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price on that date of \$1.61, was \$69,324,711.

As of March 20, 2017, the registrant had 43,058,827 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

## TABLE OF CONTENTS

	Page
<u>PART I</u>	
Item 1. Business	5
Item 1A. Risk Factors	45
Item 1B. Unresolved Staff Comments	80
Item 2. Properties	80
Item 3. Legal Proceedings	81
Item 4. Mine Safety Disclosures	81
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	82
Item 6. Selected Financial Data	82
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	83
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	94
Item 8. Financial Statements and Supplementary Data	94
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	94
Item 9A. Controls and Procedures	95
Item 9B. Other Information	95
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	96
Item 11. Executive Compensation	102
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	111
Item 13. Certain Relationships and Related Transactions, and Director Independence	114
Item 14. Principal Accountant Fees and Services	116
PART IV	
Item 15. Exhibits and Financial Statement Schedules	118
Item 16. 10-K Summary	122

### **Forward Looking Statements**

This Annual Report on Form 10-K contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties, principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "suggests," "future," "likely," "goal," "plans," "potential," "projects," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. The description of our Business set forth in Item 1, the Risk Factors set forth in this Item 1A and our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 as well as other sections in this report, discuss some of the factors that could contribute to these differences. These forward-looking statements include, among other things, statements about:

- the accuracy of our estimates regarding expenses, future revenues, uses of cash, capital requirements and the need for additional financing;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our current and future product candidates;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to obtain future reimbursement and/or milestone payments from our collaborators;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials;
- our ability to obtain additional financing;
- our use of the proceeds from our securities offerings;
- any restrictions on our ability to use our net operating loss carryforwards; and
- our ability to attract and retain key personnel.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Annual Report on Form 10-K. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K could negatively affect our business, operating results, financial condition and stock price. All forward-looking statements included in this document are based on information available to us on the date hereof, and except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this Annual Report on Form 10-K to conform our statements to actual results or changed expectations.

We have registered trademarks for Pieris<sup>®</sup>, Anticalin<sup>®</sup> and Pocket Binding<sup>®</sup>. All other trademarks, trade names and service marks included in this Annual Report on Form 10-K are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "our Company", "the Company", "Pieris", "we", "us", and "our" refer to Pieris Pharmaceuticals, Inc., a Nevada corporation, and its consolidated subsidiary, Pieris Pharmaceuticals GmbH (formerly known as Pieris AG), a company organized under the laws of Germany. Effective as of August 26, 2015 and with notification from the Amtsgericht München as of September 29, 2015, Pieris AG was transformed to Pieris Pharmaceuticals GmbH as a result of a change in the legal entity,

### **Currency Presentation and Currency Translation**

Unless otherwise indicated, all references to "dollars," "\$," "U.S. \$," or "U.S. dollars" are to the lawful currency of the United States. All references in this Report to "euro" or " $\in$ " are to the currency introduced at the start of the third stage of the European Economic and Monetary Union pursuant to the Treaty establishing the European Community, as amended. We prepare our financial statements in U.S. dollars.

The functional currency for our operations is primarily the euro. With respect to our financial statements, the translation from the euro to U.S. dollars is performed for balance sheet accounts using exchange rates in effect at the balance sheet date and for revenue and expense accounts using a weighted average exchange rate during the period. The resulting translation adjustments are recorded as a component of accumulated other comprehensive loss.

Where in this Report we refer to amounts in euros, we have for your convenience also, in certain cases, provided a conversion of those amounts to U.S. dollars in parentheses. Where the numbers refer to a specific balance sheet account date or financial statement account period, we have used the exchange rate that was used to perform the conversions in connection with the applicable financial statement. In all other instances, unless otherwise indicated, the conversions have been made using the noon buying rate of  $\in 1.00$  to U.S. \$1.05155 based on <u>www.oanda.com</u> as of December 31, 2016.

## PART I

## Item 1. BUSINESS

#### **Corporate History**

#### General

Pieris Pharmaceuticals, Inc. was originally incorporated in the State of Nevada in May 2013 under the name "Marika Inc." Prior to a reverse merger that occurred on December 17, 2014, or the Acquisition, Marika Inc. was a "shell" company registered under the Securities Exchange Act of 1934, or the Exchange Act, with a business of operating an errand concierge service online marketplace until it began operating the business of Pieris Pharmaceuticals GmbH, or Pieris GmbH, through the Acquisition on December 17, 2014. Pieris GmbH (formerly Pieris AG, a German company which was founded in 2001 by Prof. Dr. Arne Skerra, Professor at the Technical University of Munich, Germany, and Claus Schalper) continues as the operating subsidiary of the Company. As used herein, the words the "Company," "we," "us," and "our" refer to Pieris Pharmaceuticals, Inc. operating the business of Pieris GmbH as a wholly-owned subsidiary, which business continues as the business of the Company.

Pieris Pharmaceuticals, Inc. is a holding company and the sole stockholder of Pieris GmbH. The corporate headquarters and research facility of Pieris GmbH are located in Freising, Germany. Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris GmbH, was formed on February 14, 2014 to conduct research and development in Australia.

#### **Business Overview**

We are a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor microenvironment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Our proprietary Anticalin proteins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies.

Anticalin proteins are a class of low molecular-weight therapeutic proteins derived from lipocalins, which are naturally occurring lowmolecular weight human proteins typically found in blood plasma and other bodily fluids. Anticalin®-branded proteins function similarly to monoclonal antibodies, or mAbs, by binding tightly and specifically to a diverse range of targets. An antibody is a large protein used by the immune system that recognizes a unique part of a foreign target molecule, called an antigen. We believe Anticalin proteins possess numerous advantages over antibodies in certain applications. For example, Anticalin proteins are small in size and are monomeric, meaning single protein units rather than a multi-protein complex. Therefore, we believe Anticalins are generally more stable biophysically than tetrameric monoclonal antibodies, composed of four protein subunits, potentially enabling unique routes of drug administration such as pulmonary delivery. Higher-molecular-weight entities, such as antibodies, are often too large to be delivered effectively through these methods. In addition, Anticalin proteins are monovalent in structure, which means they bind to a single cell surface receptor and which may avoid the risk of cross-linking of cell surface receptors where such receptors are a therapeutic target. Antibody-mediated cross-linking can occur when each of the two "arms" of an antibody binds to a cell surface receptor and brings these receptors into close proximity, which can lead to aggressive cell growth that is characteristic of cancer. While our basic Anticalin proteins have only a single binding site and are not subject to such cross-linking, our Anticalin-branded technology is also modular, which allows us to design Anticalin proteins to bind with specificity to multiple targets at the same time. This multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as killing cancer cells. Moreover, unlike antibodies, the pharmacokinetic, or PK, profile of Anticalin proteins can be adjusted to potentially enable program-specific optimal drug exposure. Such differentiating characteristics suggest that Anticalin proteins have the potential, in certain cases, to become first-in-class drugs.

We have access to intellectual property rights directed to various aspects of our Anticalin<sup>®</sup> technology platform, allowing for development and advancement of our platform and drug candidates. We believe our ownership and/or license of our Anticalin platform provides us with a strong intellectual property position, particularly where we are seeking to address targets and diseases in a novel way and for which there is existing monoclonal antibody intellectual property.

Our core Anticalin<sup>®</sup> technology and platform were developed in Germany, and we have collaboration arrangements with major multinational pharmaceutical companies headquartered in the U.S., Europe and Japan. These include existing agreements with Daiichi Sankyo Company Limited, or Daiichi, Sanofi Group, or Sanofi, and F.Hoffmann—La Roche Ltd. and Hoffmann—La Roche Inc., or Roche. We also established a collaboration with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, in January 2017 and entered into an exclusive license agreement with Aska Pharmaceutical Co., Ltd., or Aska, in February 2017. We have discovery and preclinical collaboration and service agreements with both academic institutions and private firms in Australia, which increasingly are handled through Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris GmbH.

We believe that the drug-like properties of the Anticalin drug class were demonstrated in various clinical trials with different Anticalinbased drug candidates, including PRS-080.

Our current development plans focus mainly on four drug candidates, PRS-080, PRS-060, PRS-343 and PRS-332.

PRS-080 is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. An excess amount of hepcidin can cause functional iron deficiency, or FID, which often cannot be treated adequately with iron supplements and can lead to anemia. PRS-080 has been designed to target hepcidin for the treatment of FID in anemic patients with chronic kidney disease, or CKD, particularly in end-stage renal disease patients requiring dialysis. We believe that by blocking the actions of hepcidin, PRS-080 will serve to address anemia by mobilizing iron for incorporation into red blood cells. Furthermore, we engineered PRS-080 to have a half-life of less than a week, so that following administration, it is expected to clear from the human body in a much shorter time frame than antibodies, which typically have a half-life of two weeks or greater. We believe a shorter residence time in the body may be a superior approach for countering excess hepcidin, as physiological levels of hepcidin in these patients are relatively high (nanomolar concentration), and in theory such high concentrations will quickly saturate an administered binding drug. As a result, frequent administration of a drug may be required in order to sufficiently antagonize, or suppress the effect of, the target. The longer residence time of a mAb, could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. PRS-080 was investigated in a single-ascending dose Phase Ia trial in healthy subjects under governance by the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM). This study was completed in 2015. The next phase of clinical development is a Phase Ib, single ascending dose study in CKD patients requiring hemodialysis, which commenced in the first quarter of 2016 and completed dosing of all patients in the first quarter of 2017 in order to study safety and pharmacological activity in CKD patients. Data un-blinding and subsequent disclosure is currently planned for the second quarter of 2017. We also plan to initiate a multi-dose clinical study in CKD patients requiring hemodialysis in the second quarter of 2017, which will assess the ability of PRS-080 to elevate hemoglobin over a period of approximately four weeks.

The second Anticalin drug candidate, PRS-060, binds to the IL-4 receptor alpha-chain (IL-4RA), thereby inhibiting the actions of IL-4 and IL-13, two cytokines (small proteins mediating signaling between cells within the human body) known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases. The small size and biophysical stability of PRS-060 enables direct delivery to the lungs, through the use of an inhaler, which we believe will enable high pulmonary concentrations of the drug candidate to be achieved at substantially lower doses than would be reached with antibodies that are systemically delivered. Further, PRS-060 has a short systemic residence time, which we believe may avoid undesired target engagement

outside of the desired area in the lungs. PRS-060 is currently undergoing IND-enabling activities, and we intend to begin a Phase I clinical trial with PRS-060 in the second half of 2017.

The third Anticalin-based drug candidate, PRS-343, is a bispecific protein targeting the immune receptor CD137 and the tumor target HER2. PRS-343 is the result of a genetic fusion of a variant of the HER2-targeting antibody trastuzumab with an Anticalin specific for CD137. The mode of action of this CD137/ HER2 bispecific is to promote CD137 clustering by bridging CD137-positive T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells. PRS-343 is intended to localize CD137 activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to CD137-targeting antibodies being developed by third parties in clinical trials. PRS-343 is currently undergoing IND-enabling activities, and we intend to begin a Phase I clinical trial with PRS-343 in the second half of 2017.

The fourth Anticalin-based drug candidate, PRS-332, is a bispecific protein targeting the immune checkpoint PD-1 and another, undisclosed immune checkpoint. PRS-332 is the result of a genetic fusion of a variant of a PD-1-targeting antibody with an Anticalin specific undisclosed immune checkpoint. The mode of action of this bispecific is to simultaneously engage each immune checkpoint on a T cell, and to thereby provide a potent signal to tumor antigen-specific T cells. PRS-332 is currently undergoing preclinical evaluation and is the most advanced program included in the company's Servier collaboration.

PRS-343 and PRS-332 are members of our set of oncology drug candidates known as the 300-Series "platform within a product" opportunity in immuno-oncology. The 300-Series Anticalin proteins target immune checkpoints, like PRS-332, or, like PRS-343, immune-stimulatory proteins and define a variety of multifunctional biotherapeutics that genetically link two distinct Anticalin proteins together or, as with PRS-332 and PRS-343, an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein. Checkpoint proteins (e.g. PD-1) are proteins that help the development of an immune response or downregulate the response, for example when an infection is eliminated while co-stimulatory proteins (e.g. CD-137) upregulate the immune response.

## Strategy

Our goal is to become a fully integrated biotechnology company by discovering and developing Anticalin based therapeutics to target validated disease pathways in a unique and transformative way, and later developing and commercializing our products. We intend to take advantage of our operational experience in technology development and our history of successful partnerships and collaborations to pursue additional partnerships that will help provide us the experience we need to bring Anticalin based drug candidates to market in a number of indications. We intend to engage with partners for many of our programs in a combination of geographic and indication-based arrangements to maximize our business opportunities. We also intend to retain certain development and commercial rights on selected products as our experience in drug development grows. Key elements of our strategy include:

- Continue to build our platform by entering into new partnerships and license and collaborative arrangements and advancing our currently partnered programs. We have entered into partnership and collaborative arrangements with pharmaceutical companies in a diverse range of therapeutic areas and geographies. We have active partnerships with global pharmaceutical companies, such as Servier, Sanofi, Daiichi, Roche and Aska. Together with our partners, we intend to advance multiple drug candidates through preclinical studies and to select further drug candidates for clinical development in the future. We will also continue to seek to engage with new pharmaceutical partners that can contribute funding, experience and marketing ability for the successful development and commercialization of our current and future drug candidates.
- Advance PRS-080 in clinical trials in anemia patients. PRS-080 was investigated in a single-ascending dose Phase Ia trial in healthy subjects in 2015 under governance by BfArM This study demonstrated excellent safety and tolerability of PRS-080 as well as dose-proportional

pharmacological activity and pharmacokinetics. The inhibition of hepcidin and the subsequent change in parameters of iron metabolism such as the increase in serum iron and transferrin saturation confirmed the mode of action of PRS-080. Based on the data obtained a Phase Ib clinical study was initiated in CKD patients and was completed in the first quarter 2017. Data unblinding and subsequent disclosure is currently planned for the second quarter of 2017. We plan to initiate in the second quarter of 2017 a multi-dose clinical study in CKD patients requiring hemodialysis, which will assess the ability of PRS-080 to elevate hemoglobin over a period of approximately four weeks.

- Advance PRS-060 through IND-enabling studies and subsequently into first-in-human trial. We have a strong preclinical pipeline of Anticalin drug candidates in diverse indications such as severe asthma (PRS-060) and immuno-oncology (PRS-343). We have formulated PRS-060 for pulmonary delivery by inhalation; have developed a bioprocess that has generated GMP material for use in preclinical safety and tolerability studies and first in human clinical studies. We intend to pursue a first-in-human clinical trial for PRS-060 in 2017.
- Advance PRS-343 through IND-enabling studies and subsequently into first-in-patient trial. PRS-343 has been advanced through IND-enabling studies in 2016, including preclinical safety and efficacy studies. We intend to file an IND and pursue a Phase I clinical trial in HER2 positive solid tumor for PRS-343 in 2017.
- Advance PRS-332 to development candidate nomination and initiate IND-enabling activities. PRS-332 is the most advanced drug candidate included in the Servier collaboration.
- **Pursue and broaden opportunities for our Anticalin technology.** We intend to continue to identify, vet and pursue opportunities to develop novel Anticalin therapeutics for oncology, pulmonary diseases, and a variety of additional diseases, as we continue to improve on the Anticalin platform technology.

### Anticalin platform technology

Our platform technology focuses on low molecular-weight Anticalin proteins that bind tightly and specifically to a diverse range of targets. Anticalin proteins are derived from human proteins called lipocalins, which are naturally occurring low-molecular weight human proteins of approximately 18 to 20kDA molecular mass typically found in blood plasma and other bodily fluids. The lipocalin class of proteins defines a group of extracellular specific-binding proteins that, collectively, exhibit extremely high structural homology, yet have an uncharacteristically low amino acid sequence identity (less than 20%), making them attractive "templates" for amino acid diversification. Lipocalins naturally bind to, store and transport a wide spectrum of molecules. The defining attributes of the 12-member human lipocalin class and, by extension, Anticalin proteins, engineered from the lipocalin class of proteins, are a four-loop variable region and a rigidly conserved beta-barrel backbone, which, together, form a cup-like binding pocket. The graphic below shows both tear (left) and NGAL (right) lipocalins together with their natural ligands.

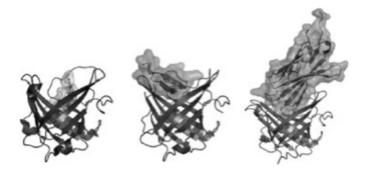


Anticalin proteins are created from either tear lipocalin, found in human tear fluid, or NGAL lipocalin, a protein involved in the innate immune system, by making discreet mutations in the genetic code for the binding regions. These mutations have the potential to lead to highly specific, high-affinity binding for both small and large molecular targets. Random mutations are introduced at pre-defined positions involved in endogenous ligand engagement, creating exponentially diverse pools of Anticalin proteins, the most potent and well behaved of



which are selected and optimized in a customized manner through *in vitro* selection. Using techniques such as phage display, a successful technique in antibody-based drug discovery, to build and refine antibody libraries, the ability to introduce diversity and then select for the best binders among a large pool of Anticalin proteins gives us the opportunity to select Anticalin proteins for a wide variety of targets. The flexibility inherent in the Anticalin proteins' cup-like structure allows us to choose both small-molecule targets that fit inside the 'cup' as well as larger protein targets that can be bound by the Anticalin proteins' outward-facing arms. Our Phase Ia trial for PRS-080 indicated that Anticalin proteins may be non-immunogenic and thereby have the potential to exhibit a favorable safety profile.

The below graphic demonstrates Anticalin drug candidates binding to a small molecule (left), a small protein target (hepcidin, center) and a large protein target (CTLA4, right):



To obtain a specific Anticalin protein, we take advantage of the breadth of our proprietary Anticalin libraries, generated through our protein engineering expertise. We have created, and will continue to create, proprietary Anticalin libraries by rationally diversifying the lipocalin regions that are responsible for ligand binding, applying different libraries to different types of targets. By utilizing bacterial production from the earliest stages of drug discovery through Current Good Manufacturing Practice, or cGMP, manufacturing, we have created a seamless platform that improves the quality, yield and cost-effectiveness of our drug candidates. However, Anticalin protein manufacturing is not limited to bacterial systems, with the underlying expression system being driven on a program-by-program basis. See "— Manufacturing" below.

As targeted, protein-based molecules, Anticalin proteins also function similarly to monoclonal antibodies, thereby offering many of the same favorable qualities, including:

- High specificity to their targets. Like monoclonal antibodies, Anticalin proteins can bind their targets without binding other molecules, even molecules with very similar chemical structures or amino acid sequences, allowing for more effective treatments through, for example, minimizing off-target effects.
- *Tight binding and effective biological activity at their targets*. Like monoclonal antibodies, Anticalin proteins are able to bind their targets at subnanomolar affinities. Anticalin proteins can potentially achieve desirable biological effects by inhibiting an undesired or inducing a desired cell activity by binding to cell-surface receptors or their ligands.
- Human origin. Like many monoclonal antibodies in development and marketed today, Anticalin proteins are derived from a
  natural class of circulating human proteins. Their human origin increases the likelihood that Anticalin proteins will not be
  recognized as foreign by the immune system and subsequently rejected.
- *Scalability for large-scale production*. Like monoclonal antibodies, Anticalin proteins lend themselves to large-scale production, yet can also be produced in a range of expression systems ranging from prokaryotic (bacterial) to eukaryotic (animal, plant, fungal) cells. Anticalin proteins can take advantage of several well-understood and widely practiced methods of protein production both in small amounts for preclinical testing and at larger scale for clinical trials and commercial production.



While often compared to monoclonal antibodies, Anticalin proteins, we believe, offer several advantages over antibodies, including:

- Small size and biophysical stability. Anticalin proteins are small in size and are monomeric. Therefore, we believe Anticalins are generally more stable biophysically than tetrameric monoclonal antibodies, which will potentially enable unique routes of administration to target diseases, such as pulmonary delivery. Higher-molecular-weight entities such as antibodies are often too large to be delivered effectively through these methods. We believe Anticalin proteins will also be less expensive to manufacture than antibodies due to their lower molecular weight and less bulky structure as well as the ability to use the prokaryotic-based manufacturing systems, a less costly manufacturing system than mammalian cell-based manufacturing systems, to create them.
- *Optimization of half-life*. Anticalin proteins can be engineered to have a half-life that is optimal for the indication area and a desired dosing schedule. Antibodies typically have half-lives of two weeks or longer, whereas Anticalin proteins can be engineered to have half-lives from hours to weeks, depending on the half-life extension technology employed, if any. This optionality allows us to exert greater control over the amount of circulating Anticalin protein in the blood and the amount of time such Anticalin proteins circulate in the blood, depending on the underlying biology we are trying to address.
- Modular platform for higher-order multispecificity and avoidance of cross-linking. Our Anticalin technology is modular, allowing for monovalent or multivalent target engagement, including multispecificity within a single protein. We believe that a monovalent "backbone" is an advantage in situations where pure antagonism of certain cellular receptors is desired. The dual-binding nature of monoclonal antibodies, which have two "arms," can be a disadvantage in cases when the antibodies bind to and cross-link cell-surface receptors. Such cross-linking often leads to undesirable activation of the cells bearing those receptors. Single-action (monovalent) Anticalin proteins have only a single binding site and are thus not subject to cross-linking. Further, when it is called for by the biology we are addressing, we can create multispecific Anticalin proteins that can simultaneously bind (i) two or more different targets or (ii) different epitopes, the specific piece of an antigen to which an antibody binds, on the same target by genetically linking Anticalin proteins with distinct specificities on a common cDNA strand. We believe this multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as killing cancer cells. Unique Anticalin proteins can be pieced together and undergo simultaneous target engagement as a single fusion protein, without generally compromising on manufacturability.

## Implementation of our Anticalin Platform Technology: Our Drug Candidates Pipeline

Each of our drug candidates is in the early stage of development, and we anticipate that it will likely be several years before any of our drug candidates could be commercialized. The following table summarizes the status of our current drug candidates and programs:

Product Candidate and Target	Indication	Stage of Development				
		Preclinical	IND Enabling Studies	Phase 1b/2a	Upcoming Milestone(s)	Commercial Rights
PRS-080 targeting Hepcidin	FID, Anemia of chronic kidney disease	>		$\supset$	<ul> <li>Planned disclosures of blinded data from Phase Ib in patients in second half of 2017</li> <li>Planned Phase 2a study to begin in 2017</li> </ul>	Pierls
PRS-343 targeting CD137 (4-18B) and HER2	Immuno Oncology	>	$ \longrightarrow $		<ul> <li>Planned Phase I clinical study to begin in first half of 2017</li> </ul>	Pieris
PRS-060 targeting IL-4RA	Asthma	>	$\supset$		<ul> <li>Expect to complete IND Enabling Studies in 2017</li> <li>Planned Phase I clinical study to begin in 2017</li> </ul>	Pieris
PRS-332 targeting an undisclosed checkpoint target	Immuno Oncology	$\sum$			<ul> <li>Expect to nominate a development candidate and initiate IND- enabling activities in 2017</li> </ul>	Pieris = US Servier = Res of world

### PRS-080 targeting hepcidin in CKD-related FID-anemia

PRS-080 is an Anticalin drug candidate targeting hepcidin, a peptide mediator that is an important negative regulator of iron absorption and storage, derived from the naturally occurring human lipocalin known as NGAL. The normal function of hepcidin is to maintain equilibrium in iron supply for red blood cell production by binding to ferroportin, the protein that transports iron from the inside of a cell to the outside, inducing its internalization and subsequent degradation. The binding of hepcidin to ferroportin reduces the iron uptake from the intestine into the body and inhibits iron mobilization from cellular stores into red blood cells. An excess amount of hepcidin can cause FID, which often cannot be treated adequately with iron supplements and can lead to anemia. According to a 2009 publication by Young and Zaritsky in the Clinical Journal of the American Society of Nephrology, lowering hepcidin levels or antagonizing its actions would reverse the negative effects of inflammation on red blood cell formation by allowing mobilization of stored iron and improved iron absorption.

PRS-080 has been designed to target hepcidin for the treatment of FID in anemic patients with CKD, particularly in end-stage renal disease patients requiring dialysis, to allow them to mobilize iron that is trapped in iron storage cells for use in the creation of red blood cells. We have also engineered PRS-080 to have a half-life of less than a week, so that following administration, it is expected to clear from the human body in a much shorter timeframe than antibodies, which typically have a half-life of two weeks or greater. This half-life was achieved by covalently linking PRS-080 to a specific polyethylene glycol, or PEG, in order to extend the serum half-life of the combined molecule to desirable levels. Since hepcidin is constantly produced by the body, we believe that a frequent, e.g. once per week, dosing interval will be optimally suited to interfere with hepcidin function. A half-life of about three days and a shorter residence time than mAbs is then in turn more compatible with the dosing schedule. A longer mAb-like residence time is not seen as advantageous, but rather could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. We completed a Phase Ia single-ascending dose clinical trial with PRS-080 in healthy volunteers in 2015. The trial was conducted in accordance with German law at a clinical site in Neu-Ulm, Germany, that belongs to Nuvisan GmbH, our contract research organization, or CRO. Results from this trial were presented at the 2015 Annual Conference of the American Society of Hematology (http://www.bloodjournal.org/content/126/23/536). Based on the data obtained we initiated a Phase Ib clinical study in CKD 5 patients requiring hemodialysis which we completed in February 2017. Data un-blinding and



subsequent disclosure is currently planned for the second quarter of 2017. The company plans to initiate a multi-dose clinical study in CKD patients requiring hemodialysis in the second quarter of 2017, which will assess the ability of PRS-080 to elevate hemoglobin over a period of approximately four weeks.

#### Chronic kidney disease

According to the American Kidney Fund, approximately 31 million individuals in the United States have CKD (Stages 1-5). The proportion of CKD patients with anemia increases with the severity and stage of CKD. However, according to a September 2013 competitive landscape report conducted by Tech Atlas Group, overall rates of individuals with anemia among the CKD population are approximately 30%, and according to a 2004 study by McClellan et al., Current Medical Research and Opinion, approximately 47% of the CKD patients studied were found to be anemic. Extrapolating these percentages based on the CKD population of 31 million individuals. We believe that approximately 9.3 to 14.6 million individuals with CKD in the United States are anemic. CKD (Stage 5), also known as End-Stage Renal Disease, or ESRD, is the final stage of chronic kidney disease with approximately 640,000 patients in the U.S. as of December 31, 2012 according the U.S. Renal Data System, USRDS 2014 Annual Data Report. The Tech Atlas Group report also estimates that approximately 70%, or approximately 450,000, of CKD (Stage 5) patients suffer from anemia. Anemia related to CKD is currently treated by injectable recombinant protein erythropoiesis, (red blood cell production) stimulating agents, or rESAs—including Epogen, Aranesp, and Procrit—often combined with iron supplementation and/or a red blood cell transfusion. Based on the reported revenues of companies that market and sell rESAs, we believe that global sales of injectable rESAs were \$6.3 billion in 2012, the vast majority of which were for renal indications.

#### Anemia and functional iron deficiency in the CKD population

Anemia is a serious medical condition in which blood is deficient in red blood cells, and hemoglobin, leading to inadequate oxygen delivery to tissues and cells throughout the body. Anemia is generally said to exist when hemoglobin is less than 13 g/dL in men and 12 g/dL in women. Anemia has a number of potential causes, including nutritional deficiencies, iron deficiency, bone marrow disease, medications, and abnormalities in production of or sensitivity to erythropoietin, a hormone that controls red blood cell production. Anemia is a frequent and severe consequence of CKD. In addition, within the CKD population, anemia may be caused by FID. FID exists when, despite adequate stores, iron cannot be mobilized for erythropoiesis. In this case, despite treatment with exogenous erythropoietin and iron supplements, "functional" iron is still deficient. FID-anemic patients can be identified and selected for therapy using marketed laboratory tests for iron metabolism. The USRDS 2014 Annual Data Report estimates that as of 2012, approximately 409,000 individuals with ESRD are presently on hemodialysis. According to the results of a 2013 research analysis conducted for us by Artisan Healthcare Consulting, which, among other things, pooled research results from nephrologists in the United States, approximately 82% of the hemodialysis patient population are anemic, and that among the anemic hemodialysis patient population, up to 23% are FID-anemic. Based on the estimated 409,000 individuals with ESRD on hemodialysis, we believe that approximately 335,000 ESRD patients on hemodialysis are anemic and approximately 0.08 million individuals are FID-anemic.

Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases, and death. These morbidity and mortality risks have been clearly shown in the CKD population, where in patients age 66 and older, anemic patients with mid-stage CKD (Stage 3) have a 149% increase in cardiovascular events, and patients with severe CKD (Stage 4 and 5) have a 24% increase in cardiovascular events, in each case versus non-anemic patients in the same group, according to a paper published in 2006 in the peer-reviewed journal *Blood*. Similarly, compared to non-anemic patients, anemia increases the mortality rate by 199% in mid-stage CKD, and 59% in severe CKD. Successful treatment of anemia significantly improves patients' quality of life, especially with respect to vitality, fatigue and physical function. In addition, patients whose anemia has been successfully treated have demonstrated lower mortality rates, less frequent hospitalization, and decreases in cardiovascular morbidity.



#### Challenges in using conventional therapy

We believe CKD patients with FID-anemia are especially poorly served. These patients have adequate stores of iron but this iron is not efficiently incorporated into red blood cell precursors through rESAs and iron supplements. According to the 2009 publication by Young and Zaritsky in the Clinical Journal of the American Society of Nephrology, this imbalance in iron metabolism is a result of a high level of circulating hepcidin in the blood stream. We believe existing therapies are limited in that they do not have an impact on hepcidin or, in the case of rESAs, patients often become resistant to the therapy.

#### Our potential solution: binding hepcidin with PRS-080

We have engineered PRS-080 so that it binds to hepcidin and reduces the impact of hepcidin's negative regulation on iron mobilization. We believe that by blocking the actions of hepcidin, PRS-080 will serve to address anemia by mobilizing iron for incorporation into red blood cells.

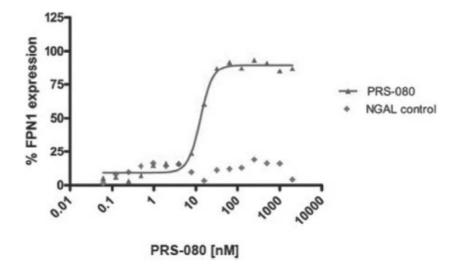
In patients suffering from anemia of CKD, and specifically in patients with FID, hepcidin is chronically produced by the body in abnormally large amounts. Therefore, we believe that the best way to inhibit its function is to administer an inhibitor on a repeated basis, such as once a week. Our approach will use PRS-080 in connection with a conjugated PEG30 molecule, a well-known half-life extender, in order to allow the drug sufficient residence time in the body. Once coupled to PEG30, PRS-080 is intended to have a half-life that will be optimally suited for dosing anemic patients with CKD. In contrast, antibodies typically have a half-life of two to three weeks. Such a long half-life renders antibodies unsuitable for frequent administration and elimination of a circulating target protein like hepcidin because such antibodies tend to accumulate the target after binding due to their own long residence time in the body with the associated risk of bound hepcidin being released by antibodies that are still circulating in the blood.

### Preclinical data

Our preclinical studies targeted the cynomolgus monkey orthologue of hepcidin, which has a high degree of similarity (96% identity) with human hepcidin. PRS-080 was found to bind with high affinity to the cynomolgus monkey version of hepcidin. We performed a dose finding study in cynomolgus monkeys, testing intravenous 30-minute infusions as well as subcutaneous injections of PRS-080. We also carried out a 4-week repeated dose toxicology study with intravenous infusions of PRS-080 for 30 minutes every other day. Our work included toxicokinetic and ADA measurements. During the study, safety pharmacology parameters on the cardiovascular system and respiration were monitored and all safety endpoints were met. Our preclinical studies also examined a different NGAL-derived Anticalin, or surrogate molecule, which targets rat hepcidin in a rat model of inflammation-induced anemia. In these studies, administration of the surrogate molecule once per day or every other day inhibited the manifestation of anemia in the rats over the course of a three-week period.

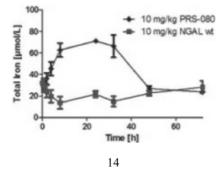
Hepcidin binds to ferroportin and induces its internalization and subsequent degradation, thus disabling iron mobilization from cells. PRS-080 binds strongly to hepcidin and inhibits its activity as shown in potency assays. These in vitro potency studies showed that the hepcidininduced internalization of ferroportin is inhibited by PRS-080 in a dose-dependent manner. PRS-080 allowed for the restoration of ferroportin expression, overcoming the hepcidin-induced down-regulation, whereas NGAL alone did not have a similar effect on ferroportin expression.

The below chart demonstrates the percentage of expression of ferroportin, % FPN1, by PRS-080 mediated inhibition of hepcidin in an in vitro potency assay with ferroportin transfected 293 cells, wherein at 20 nM, hepcidin induces internalization of ferroportin which is reversed by PRS-080 in a dose dependent manner:

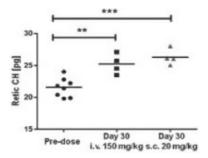


We then studied the functional consequences of hepcidin inhibition on iron mobilization in cynomolgus monkeys. A dose of 1 mg/kg PRS-080 produced a robust, transient and reversible increase in total iron levels from approximately 36  $\mu$ M at baseline to 52  $\mu$ M after 8 hours. Doses higher than 1 mg/kg elevated serum iron concentrations to comparable levels and, in a dose-dependent manner, prolonged the response. A linear correlation was observed over time between the PRS-080 dose and increase of serum iron concentrations.

The below chart shows the increase in serum iron concentrations in cynomolgus monkeys following a single intravenous administration of PRS-080 at 10 mg/kg compared to wild-type NGAL administered at the same dose:



The functional consequence of PRS-080 treatment on bone marrow activity and red blood cell production, or hematopoiesis, by means of hemoglobin (an oxygen transporting protein contained in red blood cells) concentration in reticulocytes, a precursor of red blood cells, was investigated in cynomolgus monkeys following repeated administration. As shown in the below chart, after administration of PRS-080 either intravenously (i.v. 150 mg/kg) or subcutaneously (s.c. 20 mg/kg), elevated hemoglobin concentrations in reticulocytes (Retic CH) were observed on day 30 compared to pre-treatment (pre-dose).



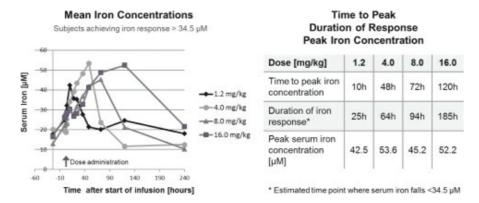
The PK properties of PRS-080 were investigated in cynomolgus monkeys after a single administration at doses ranging from 20 mg/kg to 150 mg/kg. The concentration over time profiles of PRS-080 showed standard drug-like properties, as the kinetics were dose proportional and there was a low volume of distribution. Elimination of PRS-080 occurred with a terminal half-life of about 2 days, which can be extrapolated to translate to 3 days in humans.

PRS-080 administration to cynomolgus monkeys was well tolerated up to the highest tested dose of 120 mg/kg. This dose was classified as producing no adverse events: routine laboratory tests and blood cell examinations did not demonstrate any adverse findings and safety pharmacology investigations were without adverse events. As a result of the hepcidin inhibition, the study showed increased iron uptake and storage, for example in the liver, and mobilization.

#### Phase I trial design and results

The Phase Ia trial of PRS-080 was conducted in healthy volunteers at a clinical site in Neu-Ulm, Germany by Nuvisan GmbH, a CRO. The study was a single dose escalating, blinded, placebo controlled study at a dose range from 0.2 to 40 mg/kg (equivalent to 0.08 to 16.0 mg/kg based on protein content). Forty-eight subjects were dosed with PRS-080 or a placebo. This study was governed and approved by the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM) and the local Ethics Committee. Treatment of subjects began at the end of 2014 and was completed in June 2015, followed by evaluation of the data.

PRS-080 was well tolerated. All treatment emergent Adverse Events, or AEs, were either mild or moderate and no Serious AEs were observed. No association of AEs to specific organs and no apparent dose dependency or difference between placebo and active treatment was observed. Notably, no hypersensitivity or infusion reactions were noted and vital signs, body temperature and electrocardiograms were unchanged. Pharmacokinetics of PRS were dose-proportional with a half-life of approximately 3 days. PRS-080 administration resulted in an immediate decrease in plasma hepcidin concentration, which was followed by an increase in serum iron concentration and transferrin saturation. As shown in the figure below, the duration of this response in iron and transferrin saturation increased dose-dependently from about 25 hours at the lower dose to about 185 hours at the highest dose.



### Phase Ib trial in anemic CKD 5 patient

Based on this positive safety and pharmacological activity we initiated a Phase lb study in CKD 5 patients undergoing hemodialysis and suffering from FID-anemia earlier in 2016. This study was completed in the first quarter of 2017. Results will be available in the second quarter of 2017. Patients are being treated with a single PRS-080 administration at 2 mg/kg, 4 mg/kg and 8 mg/kg. Safety, pharmacokinetics and pharmacological activity by means of serum iron and transferrin saturation will be investigated. Subsequently, we plan to investigate repeated administrations of PRS-080 in a Phase 2a study to investigate the effects of hepcidin inhibition and iron mobilization on hemoglobin levels in CKD patients. This Phase 2a study is planned to start in the second quarter of 2017.

### PRS-343 targeting CD-137 in oncology

PRS-343 is a bispecific protein targeting the immune receptor CD137 and the tumor target HER2. It is generated by genetic fusion of an Anticalin specific for CD137 with a variant of the HER2-targeting antibody trastuzumab. The mode of action of this CD137/HER2 bispecific is to promote CD137 clustering by bridging CD137-positive T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells. PRS-343 is intended to localize CD137 activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to CD137-targeting antibodies being developed by third parties in clinical trials. PRS-343 has been advanced through IND-enabling studies in 2016, including preclinical safety and efficacy studies were performed. We have completed a Master Cell bank was generated and GMP material to support initial clinical trials. We intend to file an IND and pursue a Phase I clinical trial in HER2 positive solid tumor for PRS-343 in the first half of 2017.

#### Biology of the costimulatory immune receptor CD137

CD137, also known as 4-1BB, is a co-stimulatory immune receptor and a member of the tumor necrosis factor receptor, or TNFR, superfamily. It is mainly expressed on activated CD4+ and CD8+ T cells, activated B cells, and natural killer, or NK, cells. CD137 plays an important role in the regulation of immune responses and thus is

a target for cancer immunotherapy. CD137 ligand (CD137L) is the only known natural ligand of CD137, and is constitutively expressed on several types of antigen-presenting cells, or APC. CD137-positive T cells are activated by engaging a CD137L-positive cell. The induced CD137 clustering leads to activation of the receptor and downstream signaling. Note that the trimeric CD137L as a soluble molecule is not an effective CD137 agonist, providing evidence that larger scale clustering is required for activation. In a T cell pre-stimulated by the T cell receptor binding to a cognate Major histocompatibility complex, or MHC, target, costimulation via CD137 leads to further enhanced activation, survival and proliferation, as well as the production of pro-inflammatory cytokines and an improved capacity to kill.

### Validation of CD137 as a therapeutic target in cancer

The benefit of CD137 costimulation for the elimination of cancerous tumors has been demonstrated in a number of in vivo models in the mouse. The forced expression of CD137L on a tumor, for example, leads to tumor rejection. Likewise, the forced expression of an anti-CD137 single chain antibody fragment (scFv) on a tumor leads to a CD4+ T-cell and NK-cell dependent elimination of the tumor. A systemically administered anti-CD137 antibody has also been demonstrated to lead to retardation of tumor growth.

Human ex vivo data support the extraordinary potential of CD137 as a costimulatory receptor in cancer therapy: It has been reported that for T cells isolated from human tumors, CD137 is an effective marker for those that are tumor-reactive. Based on this observation, we believe anti-CD137 antibodies can be utilized to improve adoptive T-cell therapy (ACT) by augmenting the expansion and activity of CD8+ melanoma tumor-infiltrating lymphocytes.

Finally, the potential of CD137 targeting has also been shown in nonclinical combination therapy studies, where an additional benefit was demonstrated by combination of CD137 agonism with checkpoint blockade or NK cell-targeting antibodies.

## Current approaches to clinical CD137 targeting

The preclinical demonstration of the potential therapeutic benefit of CD137 costimulation has spurred the development of therapeutic antibodies targeting CD137, PF-05082566 (22, 23) and BMS-663513, which are currently in early phase clinical trials.

PF-05082566 is a fully humanized IgG2 monoclonal antibody that binds CD137 in a manner that blocks the binding of endogenous CD137L to CD137, and that according to publicly available data is well tolerated as a monotherapy and in combination with rituximab.

BMS-663513 is an IgG4 monoclonal antibody that, in contrast to PF-05082566, binds CD137 in a manner that does not interfere with the CD137 / CD137L interaction. While an initial trial reported manageable toxicity with doses up to 10mg/kg, a follow-up monotherapy phase II trial was reported to have been stopped due to an "unusually high incidence of grade 4 hepatitis". Current clinical trials with BMS-663513 are focusing on safety and efficacy at lower doses as monotherapy or in combination e.g. with Rituximab (NCT01775631).

## Rationale for bispecific targeting of CD137

We believe that the natural mode of activation of CD137, which requires receptor clustering, demonstrates that an ideal CD137-targeting agent should firstly lead to clustering of CD137, and secondly do so in a tumor-localized fashion on tumor-infiltrating lymphocytes or TIL. The antibodies currently in clinical development are not ideal in that respect, as CD137 clustering can only be induced by binding to Fcg receptor-positive cells, which are not selectively tumor-localized but distributed throughout the body for Fcg-dependence of TNFR targeting). The toxicity data of BMS-663513 indicates that such a non-selective activation leads to unacceptable toxicity, potentially making it impossible to find a therapeutic window for such CD137-targeting antibodies.

We therefore hypothesized that to obtain an ideal CD137-targeting agent, a bispecific molecule should be designed that targets CD137 on one end and a differentially expressed tumor target on the other end. A visualization of the general concept is provided in Figure 1, below.HER2/CD137 bispecific is envisioned to promote CD137 clustering by bridging T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells, further enhancing its T cell receptor, or TCR,-mediated activity and leading to tumor destruction.

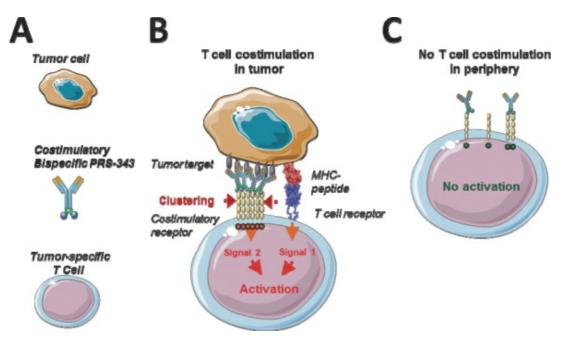


Figure 1 Concept of costimulatory T cell engagement. (A) The elements of the system are a target-positive tumor cell, a T cell with a TCR that is specific for an HLA/peptide combination on the tumor, and a costimulatory bispecific. (B) Within a patient's tumor, tumor-specific T cells are bridged with tumor cells by a costimulatory bispecific. The resulting clustering of the costimulatory T cell receptor provides a local co-activating signal to the T cell, further enhancing its TCR-mediated activity and leading to tumor destruction. (C) Toxic side effects are expected to be manageable, as target-negative cells do not lead to costimulation of T cells due to a lack of target-mediated receptor clustering, and healthy tissue is spared by tumor-costimulated T cells due to the absence of a primary, TCR-mediated signal. *Design and Generation of HER2/CD137 bispecific PRS-343* 

To obtain a molecule that would work by the mode of action of costimulatory T cell engagement, we generated the HER2/CD137 bispecific PRS-343. The molecule consists of two different building blocks binding to the two targets HER2 and CD137. To generate the CD137-specific building block of PRS-343, termed S0575.04J10, we utilized anticalin technology. This technology works by engineering lipocalins to bind any desired target protein with high affinity and specificity, in a manner very similar to antibodies. The lipocalin family comprises a diverse group of mostly secreted soluble proteins that bind, store and transport a broad spectrum of molecules, ranging from small molecules to proteins. Lipocalins are structurally related by possessing an 8-stranded beta-barrel structure. Lipocalin-2, also known as neutrophil gelatinase-associated lipocalin, or NGAL, is a component of granules in neutrophils and is up-regulated during inflammation. The primary function of NGAL appears to be the sequestering of bacterial siderophores (iron chelators), leading to an inhibition of bacterial growth. A CD137-binding anticalin was generated based on a re-design of the natural binding pocket of NGAL using mutant anticalin libraries and a selection and screening process. The CD137-binding anticalin S0575.04J10 binds human



CD137 with an affinity of 2 nM as determined by SPR, and is capable of costimulating human T cells when immobilized on a plastic dish together with an anti-CD3 antibody.

To generate the HER2/CD137 bispecific PRS-343, we constructed a genetic fusion of the CD137-specific anticalin S0575.04J10 to the C-terminus of the heavy chain of the trastuzumab IgG4 variant, connected by a flexible, non-immunogenic linker sequence of 15 amino acids length.

We utilized a Sandwich ELISA experiment to investigate whether PRS-343 can bind both targets at the same time, which is a necessary prerequisite for the envisioned mode of action of PRS-343. Figure below shows that a sigmoid binding curve results from this titration, proving that both targets can indeed be engaged at the same time, fulfilling the key requirement for simultaneous costimulatory engagement of T cells by HER2-positive target cells.

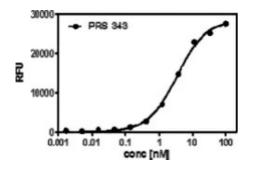


Figure 2 PRS-343 simultaneous binding to targets HER2 and CD137. Recombinant Her2 was coated on a microtiter plate, followed by titration of PRS-343. Subsequently, a constant concentration of biotinylated human CD137 was added, which was detected via a peroxidase-conjugated avidin variant, ExtrAvidin®.

#### Mode of action - costimulatory T cell activation

We developed a novel T cell activation assay format to investigate whether PRS-343 is capable of costimulating T cells that have received a basic stimulus via the TCR. The assay, visualized in Figure 3 below, is based upon providing the T cell receptor stimulus via an anti-CD3 antibody coated onto the plastic culture dish, while CD137 costimulation is achieved by tumor-target dependent clustering of CD137 on purified T cells.

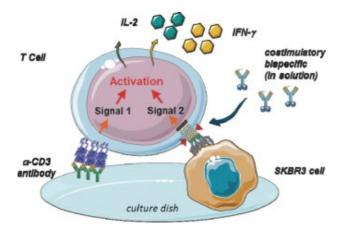
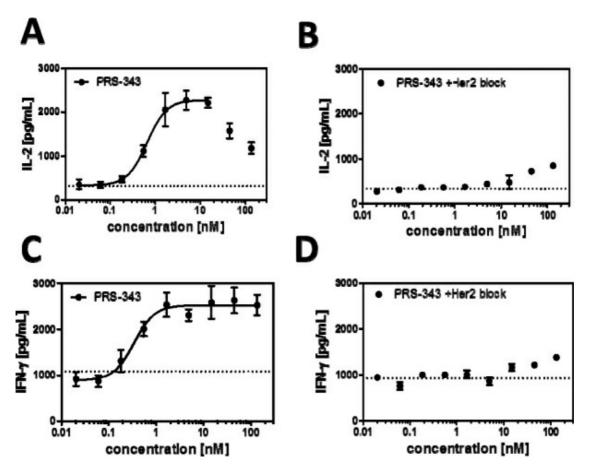


Figure 3 Visualization of costimulatory T cell activation assay. HER2-positive tumor cells are grown overnight on cell culture plates that have been precoated with low amounts of an anti-CD3 antibody to provide a limited primary activation of T cells via the T cell receptor. T cells are added to the wells together with *the titrated CD137/HER2 bispecific PRS-343, leading to clustering of the costimulatory CD137 receptor, which in turn results in T cell costimulation. T cell costimulation is detected by increased supernatant IL-2 and IFN-g levels in the culture supernatants after continued culture.* 

There is a clear induction of IL-2 (Figure A) and IFN-g (Figure C) with increasing concentrations of PRS-343. The fitted EC50 of this effect is similar for both proinflammatory cytokines, with 0.7 nM for IL-2 induction and 0.3 nM for IFN-g induction, respectively. That T cell costimulation is indeed, due to the bispecific engagement of T cells and SKBR3 cells, shown by two observations: firstly, the monospecific antibody trastuzumab does not lead to enhanced T cell activation (average shown as dotted line in Figure A and Figure C), and secondly, disrupting the bispecific interaction with an excess of trastuzumab abolishes the effect of IL-2 and INF-g induction almost completely, except at the highest concentrations of PRS-343 employed (Figure B and Figure D).



**Figure 4** Experimental result of costimulatory T cell activation assay. HER2-positive SKBR3 tumor cells were grown overnight on 96well plates that had been precoated with 0.25 μg/mL anti-CD3 antibody for 1 h at 37°C. The next day, T cells purified from healthy donor PBMC were added to the wells together with the titrated CD137/HER2 bispecific PRS-343 (filled circle) or trastuzumab as a control (dotted line). After three days in culture, IL-2 (A) and IFN-g, levels in the culture supernatants were

measured by an Electrochemoluminescence immunoassay. In parallel, the experiment was performed in the presence of an excess of trastuzumab (340 nM) to inhibit the binding of PRS-343 to the SKBR3 cells, and IL-2 (C) and IFN-g (D) levels were measured.

#### PRS-060 targeting IL-4RA in asthma

PRS-060 is an Anticalin drug candidate targeting IL-4RA, a cell surface receptor expressed on immune cells in the lung epithelium and submucosal layer. IL-4RA is specific to the circulating cytokine IL-4 and the closely related cytokine IL-13, both key drivers of the immune system that induce differentiation of naïve helper T cells to type 2 helper T cells, or Th2. PRS-060 is derived from human tear lipocalin, has picomolar affinity for human IL-4RA (20 pM) and has a favorable stability profile. We showed *in vitro* that PRS-060 can inhibit the activity of both IL-4 and IL-13. We have formulated PRS-060 for pulmonary delivery by inhalation, and we have developed a bioprocess that has generated GMP material for use in preclinical safety and tolerability studies and First in Human clinical studies. Pending the results of our preclinical studies, we intend to pursue a first-in-human clinical trial for PRS-060 in 2017. Some of the development of PRS-060 is conducted in Australia, where we intend to access leading pulmonologists for potential patient recruitment and to seek up to 40% or more in tax refunds from the Australian government in connection with research and development expenses related to PRS-060. We believe PRS-060 represents a first in class inhaled biologic for the treatment of asthma.

#### Asthma market

Asthma is a very common chronic airway disorder affecting approximately 300 million people worldwide according to the Global Initiative for Asthma and approximately 26 million Americans according to the U.S. Centers for Disease Control. Of these 26 million, about 7 million are children. Asthma is responsible for 13 million physician visits a year including about 2 million emergency visits in the United States, according to the American Lung Association. In 2007 asthma was responsible for \$50 billion in direct healthcare costs each year in the United States (Barnett and Nurmagambetov, 2011, Journal of Allergy and Clinical Immunology, Volume 127, pp145-152).

#### Challenges in using conventional therapy

According to a 2012 Artisan Health Care Consulting analysis, asthma affects approximately 195 million people in the U.S., Europe, Japan, Brazil, Russia, India and China. The analysis determined that approximately 16%, or 32 million, of the group studied were considered to have moderate and severe uncontrolled asthma, while approximately 60%, or 19 million, of the group of moderate and severe uncontrolled asthma studied were considered to have moderate and severe uncontrolled asthma with an elevated Th2 signature. In the majority of patients, inflammation brought about by Th2 immunity is addressed by standard asthma therapies. However, 5-10% of patients with asthma have moderate to severe disease that is not controlled with these standard of care therapies.

The current standard of care for persistent, moderate to severe allergic asthma is high dose inhaled corticosteroids or ICS often in combination with inhaled long-acting beta-adrenergic agonists, or LABA. In very severe allergic asthma, omalizumab (Xolair from Roche) is given to patients in addition to ICS/LABA combinations. Omalizumab was approved for this condition in the United States in 2003. Outside of the United States, omalizumab is approved for severe asthma. Omalizumab works by binding to the immune mediator immunoglobulin E, or IgE, and inhibiting IgE-mediated activation of mast cells and basophils, types of white blood cells. It has also been shown to impact some diseases, such as asthma, that are driven by eosinophils, another important class of immune cells. However, patient response to omalizumab has been shown to be inconsistent, as reported in a publication by McNicholl and Heaney in 2008 in the journal *Core Evidence*, which explained that in only some studies did omalizumab improve lung function. Furthermore, general asthma symptoms are also typically unaffected by omalizumab. Finally, in 2007, the U.S. Food and Drug Administration, or the FDA, issued a black box warning for omalizumab due to reported cases of anaphylaxis, a



potentially life-threatening allergic reaction suffered by some patients who had taken the drug. Despite these shortcomings, in 2012, worldwide sales of omalizumab were reported by Roche to be \$1.2 billion.

The next generation of therapies beyond omalizumab targets a broader range than just IgE mediated mechanisms. These approaches target other immune mediators, including IL-4, IL-13, Thymic Stromal Lymphopoietin or TSLP, IL-33 (which act in concert on eosinophils, B-cells, epithelial cells, goblet cells and others) and PGD2 (through stimulation of CRTH2 receptors). Asthma is associated with high levels of eosinophils, immune cells that play a role in protecting the body against infection. The creation of eosinophils can be interrupted at the early stages, while the cells are still maturing. Multiple products are in development that target eosinophils and GlaxoSmithKline's, or GSK, mepolizumab (Nucala) which targets IL-5 was approved for severe eosinophilic asthma in adults and children older than 12 in 2015. However, eosinophils are only one of many cell types and immune system components that are involved with the body's exaggerated inflammation response in asthma. Mast cells, basophils, goblet cells and other cells also play a role. These cells can be seen infiltrating the airways along with eosinophils, leading to the conclusion that more cell types are involved in asthma pathogenesis. We believe that targeting just one of these components unlikely to be as effective in treating severe asthma as an approach that targets the broader Th2 (cell-mediated) pathway.

In 2013, Regeneron and its partner Sanofi reported proof-of-concept in a Phase IIa trial in persistent asthma with dupilumab, a currently unapproved monoclonal antibody that targets IL-4RA now in clinical development as a subcutaneously delivered agent. In a 2013 paper in the New England Journal of Medicine, Wenzel et al. reported that dupilumab showed a benefit on the asthma control questionnaire 5 (ACQ5) symptom score, a widely accepted measure for classifying the ability of a medication to control asthma. Patients dosed with dupilumab had fewer asthma attacks compared to placebo-treated patients when standard therapies, such as long-acting beta-agonists and inhaled glucocorticoids, were withdrawn, demonstrating the efficacy of dupilumab. Patients also showed improved lung function and reduced levels of Th2-associated inflammatory markers. Dupilumab is administered systemically through injection. In November 2014, Regeneron and Sanofi announced that in a Phase IIb study, dupilumab also demonstrated improved lung function and reduced exacerbations when administered together with standard of care. These effects were observed in both unselected severe asthma patients and selected patients presenting elevated Th2 responses. We believe the results support the possibility of treating persistent uncontrolled asthma with a biologic therapy without narrowing the patient population based on the Th2 phenotype. Dupilumab is currently undergoing Phase 3 clinical trials for severe asthma.

Another biologic that was in development for severe asthma was lebrikizumab, which blocks the effects of IL-13, a mechanism known to have a similar effect to that of dupilumab. Like dupilumab and other mediators of the Th2 pathway, lebrikizumab is a validating example for subcutaneously delivered Th2 intervention in treating uncontrolled asthmatics. In a 2011 publication in the New England Journal of Medicine, lebrikizumab was reported to improve lung function in severe asthma patients who were also receiving standard of care inhaled glucocorticoid therapy. However, despite these positive effects, in Phase 3 trials lebrikizumab failed to meet its primary endpoint of reducing asthma exacerbations in one of the two Phase 3 studies performed. We believe that there could also be significant advantages to other routes of administration, such as inhalation, of biologics that target asthma through the Th2 pathway. If delivered by inhalation, such biologics could be dosed at much lower levels and may preferentially direct the therapy to the site of the disease, in this case the lung.

#### Our proposed solution: binding IL-4RA with PRS-060

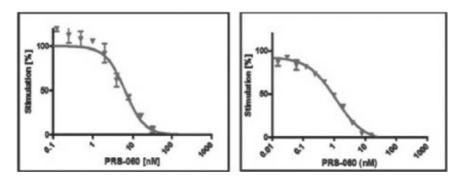
We propose to take PRS-060 forward into clinical trials first in healthy volunteers and then in moderate to severe asthma patients. These trials could accomplish two important goals: we could establish proof-of-concept for inhaled Anticalin proteins, opening up a second route of administration for our drug candidates beyond intravenous or subcutaneous injection. Following the demonstration that inhaled PRS-060 is well tolerated in healthy volunteers, we plan to perform a proof-of-concept trial in asthma patients who are uncontrolled on standard of care therapy (ICS/LABA combinations), where we will evaluate whether PRS-060 can improve lung function and asthma symptoms. We intend to begin a Phase I clinical trial for PRS-060 in the second half of 2017.

#### Advantages to inhalation as a route of administration for PRS-060

We have performed inhalation studies in mice and observed that systemic concentrations of PRS-060 are minimal when dosed by inhalation, this is because of low doses required for efficacy and short systemic residence time. This offers the potential of a wider therapeutic window and possibly lower systemic side effects that may become increasingly prevalent with chronic, systemic Th2 targeting. By our calculations, the total annual dose of PRS-060 can be significantly lower than the doses being used for the monoclonal antibodies (mAbs) dupilumab and lebrikizumab. Furthermore, we believe that PRS-060 can be produced at a lower cost of goods than mAbs because we intend to use manufacturing procedures that employ bacterial expression systems, which generally provides a cost advantage over mammalian production systems, typically used for mAbs. Since dosing by inhalation is a common route of administration in asthma patients, it represents a more convenient dosage regimen for patients than dosing of antibodies by injection. PRS-060 would therefore be self-administered using a standard device rather than requiring a visit to a physician for the drug to be given.

#### Preclinical data

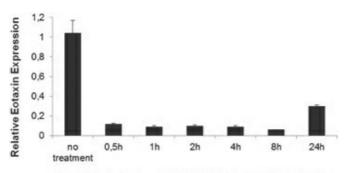
In *in vitro* assays, PRS-060 specifically bound to immobilized targets such as human IL-4RA in a concentration-dependent manner. We tested the binding of PRS-060 to various targets in enzyme-linked immunosorbent assay, or the ELISA, a standard *in vitro* assay platform. In these tests, PRS-060 bound to IL-4RA with subnanomolar affinity and it did not bind to three other human cell-surface interleukin receptors (IL-6R, IL-18RA, IL-23RA). Furthermore, the activity of IL-4 and IL-13 was inhibited by PRS-060 in a dose-dependent manner. The below charts below show the inhibition of IL-4 (left) or IL-13 (right) induced proliferation in human TF-1 cells *in vitro* by PRS-060.



In *in vivo* assays in mice genetically altered to express human IL-4RA, human IL-4 and IL-13, low doses of PRS-060 inhibited the induction of eotaxin protein, a marker or airway inflammation, in lung tissue following pulmonary delivery. We observed this inhibition at both the RNA and protein levels compared both to buffer and to tear lipocalin.



The below chart shows the duration of PRS-060-mediated inhibition of eotaxin gene expression, a marker of airway inflammation, in lung tissue by a single pulmonary dose in mice:



Time of single treatment of PRS-060 prior to IL13 challange

When we administered IL-13 into the lung, inflammation was induced as determined by eotaxin expression, which was not inhibited when phosphate buffered saline, or PBS, or human Wild Type lipocalin was administered into the lung. In contrast to the PBS administration, increases in eotaxin expression were prevented when PRS-060 was administered into the lung before IL-13. As demonstrated in the above chart, the model showed the inhibitory potential lasts for up to 24 hours after PRS-060 administration.

#### PRS-332 targeting an undisclosed checkpoint target

PRS-332 is a bispecific anticalin-antibody fusion protein comprising an anti-PD-1 antibody genetically fused to an Anticalin targeting an undisclosed checkpoint target. Other drug candidates targeting the checkpoint molecule PD-1 include nivolumab, marketed by Bristol Myers Squibb (trade name Opdivo), and pembrolizumab, traded by Merck, (trade name Keytruda). Anti-PD-1 antibodies have demonstrated great clinical benefit in several cancers, including melanoma, non-small cell lung cancer, renal cell carcinoma, Hodgkin lymphoma, head and neck carcinomas. However, there are many patients who do not respond, relapse or acquire resistance to PD-1 treatment. In order to improve on existing PD-1 therapies, Pieris is developing PRS-332 with the intent to simultaneously block PD-1 and another immune checkpoint co-expressed on exhausted T cells.

#### Pipeline products: 300 Series

Current antibody-based therapies targeting tumor cell destruction or immune activation are hampered by, among other factors, low response rates and the induction of immune-related adverse events. The 300-Series Anticalin proteins are designed to target checkpoint proteins or, like PRS-343, immune-stimulatory proteins and consist of a variety of multifunctional biotherapeutics that can combine, via a genetic fusion, antibodies with Anticalin proteins or two or more Anticalin proteins to each other. These combined molecules have the potential to build upon current therapies through the capability of modifying or regulating one or more immune functions on a single fusion protein directed at checkpoint proteins can preferentially activate the immune system at the site of the tumor microenvironment thus providing efficacy with enhanced therapeutic index. We believe that the 300-Series Anticalin proteins represent a "platform within a product" opportunity in immuno-oncology since it may be possible to apply a single combined Anticalin-antibody molecule in a number of different cancers. This is based on the shared underlying biology such as checkpoint and costimulatory biology found within tumors arising in different organs.

#### Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development

experience, scientific knowledge and strategies provide us with competitive advantages, we face and will continue to face intense competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, both in the United States and abroad.

We compete, or will compete, with existing and new therapies that may become available in the future. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our drug candidates target. Any drug candidates that we are able to develop and commercialize will compete with existing and new drugs being developed by our competitors. Our competitors may develop or market products or other novel technologies that are more effective, safer, more convenient or less costly than any that may be commercialized by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, some of which have acknowledged strategies to license or acquire products and many of which are bigger than us and have more institutional experience and greater cash flows than we have, may have competitive advantages over us, as may other emerging companies taking similar or different approaches to product licenses and/or acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines, which may provide those companies with an even greater competitive advantage.

There are a number of other companies presently working to develop therapies for anemia, asthma, and oncology, including divisions of large pharmaceutical companies and biotechnology companies of various sizes. There are also a variety of available drug therapies marketed for these diseases. Our drug candidates, if any are approved, may compete with these existing drug and other therapies, and to the extent they are ultimately used in combination with or as an adjunct to these therapies, our drug candidates may not be competitive with them. 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. As a result, market acceptance of, and a significant share of the market for, any of our drug candidates that we successfully introduce to the market will pose challenges.

In addition to currently marketed therapies, there are also a number of medicines in clinical development to treat anemia, asthma, or cancer. These medicines in development may provide efficacy, safety, convenience, and other benefits that are not provided by currently marketed therapies and may not be provided by any of our current or future product candidates. As a result, they may provide significant competition for any of our product candidates.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in some of our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build, obtain regulatory approval for and market acceptance of, and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

In addition, our competitors may have a variety of drugs in development or awaiting market approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;



- · preclinical and clinical trials of potential pharmaceutical products; and
- obtaining regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- · manufacturing capabilities; and
- sales and marketing.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved by the FDA, or its foreign counterparts, or are in advanced development. We face competition from other companies, academic institutions, governmental agencies, and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

## PRS-080

There are very few other drug candidates in development that interfere with hepcidin function or expression. Nucleic acid based approaches that were in preclinical development by IONIS/Xenon and Alnylam have been suspended for unknown reasons. Noxxon's RNA aptamer NOX-H94 has completed Phase II clinical studies in cancer and ESRD patients. While an increase of Hb values was seen in cancer patients, no such effect could be confirmed in the ESRD population. PRS-080 is significantly more potent and has a longer half-life than NOX-H94. We therefore believe that Noxxon's results are not predictive for efficacy of PRS-080. Lilly has been developing a mAb against hepcidin in cancer as well as chronic kidney disease patients as well as a mAb against the ferroportin transporter. The latter has been suspended for unknown reasons and there has been no update on the anti-hepcidin mAb from Lilly since 2014. Ferrumax develops a soluble form of hemojuvelin, a protein that regulates hepcidin expression and iron metabolism that aims to suppress the production rate of hepcidin.

There are also a number of companies which are focused on treating anemia in CKD patients under alternative approaches. Fibrogen (in partnership with Astellas and AstraZeneca), Akebia Therapeutics (in partnership with Mitsubishi Tanabe and Otsuka), GSK, Bayer, Daiichi Sankyo, Zydus Cadila and Japan Tobacco have hypoxia-inducible-factor prolyl hydroxylase (HIF-PH) inhibitors in clinical development that target stimulation of bone marrow activity. Fibrogen recently reported positive topline results from Phase III trials in China with its HIF-PH inhibitor Roxadustat (January 2017). Acceleron is targeting the sequestration of Activin A, a natural inhibitor of hematopoiesis, is in a Phase II clinical study. Auryxia by Keryx, which is an oral, absorbable, iron-based phosphate binder, completed a Phase III in non-dialysis dependent CKD 3-5 patients in 2016 and announced topline results showing that the study met the primary and all pre-specified secondary endpoints including change in Hb values. Keryx is planning to file a New Drug Application, or NDA for the CKD indication with the FDA in the near-term. There are also various companies conducting late-stage development of erythropoietin biosimilars.

## PRS-060

Like PRS-060, new developments for the treatment of uncontrolled moderate to severe asthma patients mainly include drug candidates targeting the Th2 pathway by interfering with IL4/IL-13 or IL-5 actions. Such products



include dupilumab (Sanofi/Regeneron, IL-4RA), tralokinumab (Astra Zeneca, IL-13), mepolizumab (Nucala) (GSK, IL-5), reslizumab (Teva, IL-5), and benralizumab (Astra Zeneca, IL-5R). These drugs are in later clinical development (Phase II and Phase III) than PRS-060, or have been approved (mepolizumab); however, in contrast to PRS-060, these mAbs are given to patients through injection and distribute systemically through the blood stream. There are a number of other companies presently marketing or developing other therapies for asthmatic patients. The mAb omalizumab, directed against IgE, is approved and marketed for the treatment of uncontrolled, moderate to severe asthma patients.

### PRS-300 series

Other drug candidates which target checkpoint proteins include ipilimumab, which is specific for the checkpoint protein CTLA-4 and has been marketed by Bristol Myers Squibb for the treatment of melanoma patients since 2011. Additionally, preclinical and/or clinical testing currently focusing on additional checkpoint mechanisms and targets include PD-1 / PD-L1, LAG3, IDO, TIM3, Ox-40, CD-137, CD70, KIR and NKG2A. Bristol Myers Squibb and Roche are most active in this area, with multiple single agent or combination therapy trials ongoing. Merck and AstraZeneca also have active trials ongoing, while Novartis is placing more of an emphasis on adoptive T cell transfer technology in its developmental efforts. In September 2014, Merck received FDA approval for its anti- PD-1 antibody, pembrolizumab, for the treatment of patients with advanced or inoperable melanoma.

Under the 300-Series, we are also developing multispecific molecules to facilitate the more effective activation of the immune system, with a strategy of employing multispecific Anticalin protein-based molecules that may favorably bias an immune response to the tumor microenvironment. A number of other companies, such as Amgen, Affimed, Macrogenics, F-Star and Sutro, also pursue multispecific approaches in oncology, which therapies are in clinical or preclinical development.

### PRS-343

PRS-343 is bispecific anticalin-antibody fusion protein targeting CD137 and HER2. Other drug candidates targeting the co-stimulatory receptor CD137 include urelumab, which is being developed by Bristol Myers Squibb, and PF-05082566, which is being developed by Pfizer, both of which are currently in clinical development (Biomedtracker, January 21, 2016). In the HER2-positive space, several companies are active with approved, clinical and preclinical drugs candidates. The most prominent company is Roche, having three approved drugs on the market through its subsidiary Genentech. The first drug from Roche targeting HER2 is Trastuzumab, which has been marketed for treatment of breast cancer patients since 1998 and for gastric cancer patients since 2010. The two other drugs are pertuzumab and Ado-trastuzumab Emtansine which both are marketed for breast cancer patients.

One company has publically disclosed a competitor program to PRS-343. Macrogenics presented preliminary data on a HER2 and CD137 (41BB) bispecific during their R&D day on December 13th, 2016. A number of companies such as Amgen, Affimed, F-Star, Sutro Biopharma and Immunocore are pursuing multispecific approaches in immuno-oncology, which therapies are either approved, in clinical development or preclinical development.

Additionally, other companies such as AstraZeneca, Novartis, Agenus, Five Prime Therapeutics, and Celldex have preclinical and clinical development programs focusing on other co-stimulatory targets which include OX40, CD40, GITR, and CD27.

## PRS-332

PRS-332 is a bispecific anticalin-antibody fusion protein comprising an anti-PD-1 antibody genetically fused to an Anticalin targeting an undisclosed checkpoint target. Other drug candidates targeting the checkpoint molecule

PD-1 include nivolumab, marketed by Bristol Myers Squibb (trade name Opdivo), and pembrolizumab, traded by Merck, (trade name Keytruda). Anti-PD-1 antibodies have demonstrated great clinical benefit in several cancers, including melanoma, non-small cell lung cancer, renal cell carcinoma, Hodgkin lymphoma, head and neck carcinomas. However, there are many patients who do not respond, relapse or acquire resistance to PD-1 treatment. In order to improve on existing PD-1 therapies, Pieris is developing PRS-332 with the intent to simultaneously block PD-1 and another immune checkpoint co-expressed on exhausted T cells.

Other companies such as BMS, Eli Lilly, AstraZeneca, and Hoffman La-Roche have clinical development programs focusing on the ligand PD-L1.

Additionally, other companies such as Merck, BMS, and Novartis have approved drugs or drugs in preclinical and clinical development focusing on other checkpoint targets which include CTLA-4, LAG-3 or TIM-3.

#### Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party contract manufacturers, or CMOs, for the manufacture of our drug candidates for larger scale preclinical and clinical testing, as well as for commercial quantities of any drug candidates that are approved.

We currently rely on multiple CMOs for all of our clinical supplies, including active pharmaceutical ingredients (APIs), drug substances and finished drug products, and label & packaging for our preclinical research and clinical trials, including the Phase Ia trial for PRS-080.

We believe that we will be able to contract with other CMOs to obtain APIs if our existing sources of APIs were no longer available or sufficient, but there is no assurance that APIs would be available from other third-party manufacturers on acceptable terms, on the timeframe that our business would require, or at all. We do not have long-term supply commitments or other arrangements in place with our existing CMOs. We also do not currently have arrangements in place for redundant supply of bulk drug substance.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our drug candidates if they are approved, and we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of our product candidates as they near potential approval.

Any drug products to be used in clinical trials and any approved product that we may commercialize will need to be manufactured in facilities, and by processes, that comply with the FDA's current good manufacturing practice requirements and comparable requirements of the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors.

We believe that PRS-080, PRS-060, and PRS 343 and our other Anticalin<sup>®</sup>-branded drug candidates can be manufactured in reliable and reproducible biologic processes from readily available starting materials. PRS-080 and PRS-060 are produced using bacterial expression systems similar to those that have been used in the past for the production of other proteins and which systems are widely used in the industry. PRS-343 is produced using a mammalian expression system similar to those systems which are widely used in the industry for the production of antibodies. We believe that the manufacturing process is amenable to scale-up and will not require unusual or expensive equipment. We expect to continue to develop, on our own or with our collaborators, drug candidates that can be produced cost-effectively at contract manufacturing facilities.

#### **Intellectual Property and Exclusivity**

Our commercial success depends in part on our ability to obtain and maintain exclusivity of our proprietary Anticalin®-brand technologies through intellectual property protection for our drug candidates, libraries of



different protein scaffolds and consensus sequences and the fundamental Anticalin platform technology, including novel therapeutic and diagnostic discoveries, as well as other proprietary know-how, and to operate without infringing on the intellectual property rights of others.

We seek to protect our exclusive position of Anticalin technologies by, among other means, prosecuting our own international, U.S., and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We established intellectual property protection in relation to our Anticalin technologies in key global markets, including Australia, Brazil, Canada, China, the European Union, Hong Kong, India, Japan, Korea, New Zealand, Russia, Singapore, South Africa, and the United States. We believe we have patent exclusivity relating to drug candidates derived from lipocalin proteins that runs until at least 2018 in the United States. We also rely on trade secrets for confidential know-how, which we generally seek to protect through contractual (e.g. confidentiality) agreements with employees and third parties.

We have protected the goodwill of our Company and our drug candidates, created through innovation and development, by putting in place trademark registrations of Pieris and Anticalin as well as several defensive registrations.

We currently, and expect that we will continue to, file patent applications and maintain granted patents directed to our key drug candidates in an effort to establish intellectual property positions relating to new compositions of matter for these drug candidates, as well as novel medical applications of these compounds in the treatment, prevention or diagnosis of various indications. We also intend to seek patent protection, if available, with respect to biomarkers that may contribute to selecting the right patient population for use of any of our drug candidates, or with respect to pharmaceutical formulations that may be useful to produce final medicinal products.

Following the effective date of our Research and Licensing Agreement with Technische Universität München, or TUM (See "—TUM License Agreement"), and as of March 23, 2017, we owned or were the exclusive licensee of a patent portfolio consisting of several issued U.S. patents, and their respective counterparts in a number of foreign jurisdictions, several pending applications under the Patent Cooperation Treaty, multiple pending U.S. patent applications and corresponding pending patent applications in a number of foreign jurisdictions, as described in further detail below.

In applicable jurisdictions, we will seek patent term extensions for certain patents of ours, including the patent term adjustment period in the United States. If we obtain marketing approval for our drug candidates in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as twelve years of data exclusivity for new biological entities in the United States and as mentioned below, up to five years of patent term extension potentially available in the United States under the U.S. Food, Drug and Cosmetic Act, eight to eleven years of data and marketing exclusivity potentially available for new drugs in the European Union, up to five years of patent extension in Europe (supplemental protection certificate), and eight years of data exclusivity potentially available in Japan. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See "—Government Regulation."

Among the issued patents we own are U.S. Patent No. 7,250,297; U.S. Patent No. 7,723,476; U.S. patent No. 8,158,753; U.S. patent No. 8,536,307; and their respective counterparts in the European Union, which patents are directed to the basic Anticalin protein concept and platform technology (i.e. antagonist or agonist compounds derived from a natural lipocalin protein) and are expected to expire in 2018, subject to any patent term adjustments and terminal disclaimers in the United States. In addition, we hold issued U.S. Patents Nos.: 7,001,882; 7,118,915; 7,691,970; 7,585,940; 7,893,208; 8,313,924; and 9,549,968 and their respective counterparts in a number of foreign jurisdictions, which patents are related to libraries of different scaffolds and consensus sequences such as human apolipoprotein D, human neutrophil gelatinase-associated lipocalin, or hNGAL, and human tear lipocalin, and are expected to expire between 2020 and 2030, subject to any patent term adjustments and terminal disclaimers in the United States. We also own U.S. Patent No. 7,892,827, which is

directed to muteins derived from hNGAL having binding specificity for the cytotoxic T lymphocyte-associated antigen, or CTLA-4, and is expected to expire in 2025, subject to any term adjustments and terminal disclaimers in the United States, and U.S. Patent No. 8,313,924, which is directed to muteins of human tear lipocalin having detectable binding affinity to interleukin 4 receptor alpha chain, or IL-4 receptor alpha, and is expected to expire in 2027, subject to any patent term adjustments and terminal disclaimers in the United States, as well as their counterparts in the European Union and in a number of foreign jurisdictions.

As a result of research efforts to date under the Research and License Agreement with TUM, we hold a worldwide exclusive license to multiple patents and patent applications. In the United States, we hold an exclusive license to an issued U.S. Patent No. 8,598,317 for the composition of matter of mutein of human tear lipocalin binding to the extracellular region of the T-cell co-receptor CD4 with detectable affinity, which patent will expire in 2027 subject to any patent term adjustments and terminal disclaimers in the United States, as well as to its counterpart in the European Union. We also hold an exclusive license to an issued U.S. Patent No. 8,420,051 directed to library of hNGAL scaffold of certain consensus sequence, which patent is expected to expire in 2029, subject to any patent term adjustments or terminal disclaimers in the United States, as well as to its counterparts in the European Union. Me also hold as to its counterparts in the European Union of core and terminal disclaimers in the United States, as well as to expire in 2029, subject to any patent term adjustments or terminal disclaimers in the United States, as well as to its counterparts in the European Union and in a number of foreign jurisdictions. Moreover, we hold an exclusive license to an issued U.S. Patent No. 8,987,415 claiming isolated crystalline form of monomeric bacterial lipocalin.

As of January 26, 2017, a significant portion of our pending U.S. patent applications and pending patent applications in foreign jurisdictions was directed to newly-discovered or improved scaffold libraries of lipocalin muteins, compounds derived therefrom, or the uses of such compounds to treat, prevent and mitigate certain diseases and conditions whose pathological development involve the targets of interest as well as to diagnose, prognose and select treatments for the diseases and conditions. We would expect that any patents that may issue from the pending U.S. patent applications would likely expire between 2029 and 2038 without taking into account possible patent term adjustments or other extensions, however, any and all of these patent applications may not result in issued patents, and not all issued patents may be maintained in force for their entire term. Specifically, granted patents and pending patent applications directed to Anticalin proteins for the CMet target currently have terms which could expire as late as 2029, and granted patents and pending patent applications directed to Anticalin proteins for each of hepcidin and IL-4RA currently have terms, which could expire as late as 2031. We are actively pursuing intellectual property protection for our 300-Series in key global markets that, if granted, could expire as late as 2038.

In addition to patents, we hold trademarks in the United States, for Anticalin, Pieris, and Pocket Binding. Similarly, we hold their respective counterparts, either as registered trademarks or as pending applications, in a number of foreign jurisdictions. We expect that we will continue to look for trademark protection for the goodwill associated with our Company and our drug candidates in the countries or regions where we will have investment, research and development, sales or other activities.

We also rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive advantage. We strive to protect our proprietary information, in part, by using confidentiality agreements and/or invention assignment agreements with our collaborators, scientific advisors, employees and consultants. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party. We also actively manage our publication and patent applications in that we only disclose information necessary to stir scientific interest or demonstrate patentability without materially compromising the secrecy of our valuable trade secrets and know-how. While we consider trade secrets and know-how to be a critical component of our intellectual property, trade secrets and know-how can be difficult to protect. In particular, with respect to our technology platform, we anticipate that these trade secrets and know-how will, over the course of time, be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel skilled in the technology from academic to industry positions and vice versa. As a result, those proprietary trade

secrets and know-how may lose their value to us over a period of time, and we may lose any competitive advantage afforded by them, as they become public knowledge.

#### **Strategic Partnerships**

Since 2007, we have entered into several licensing, research and development collaborations to complement our drug discovery and early stage development capabilities. Specifically, we have entered into licensing, research and development agreements, which are still active as of the date hereof with Allergan, Inc., or Allergan, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA) and collectively, Sanofi, Daiichi Sankyo, Roche, Servier and Aska. Under these licensing and research and development arrangements, we have developed and conducted or will develop and conduct selection and screening of drug candidates, as well as *in vitro* potency and efficacy testing, using our Anticalin<sup>®</sup>-brand drug discovery platform, our Anticalin-brand libraries, and other proprietary methods to generate, identify, and characterize drug candidates against certain biological targets associated with several diseases. These agreements have provided us with approximately  $\in$ 38.6 million (\$42.1 million) in revenue to date, excluding grant revenues. With respect to discontinued collaborations, we have no ongoing performance obligations, and do not expect to receive any significant additional consideration pursuant to those agreements.

Pieris's agreements with Allergan, Sanofi, Daiichi Sankyo, Roche, Servier and Aska are ongoing and, under which, our partners are obligated to use commercially reasonable efforts to develop and commercialize drug candidates identified in the course of the collaboration. We are entitled to receive from our partners' research, development and regulatory milestone payments and, in the case of the Sanofi, Daiichi Sankyo, Roche, Servier and Aska collaborations, royalties on net sales for products developed and commercialized under these collaborations. We plan to continue to actively seek out additional collaboration partners.

In addition to Pieris's agreements with Allergan, Sanofi, Daiichi Sankyo Roche, Servier, and Aska, we are partnering with companies with expertise in clinical development, regulatory affairs and biologics manufacturing to advance our pipeline products through clinical trials and to market those products. In 2013, Pieris entered into a co-development alliance with Cadila Healthcare Limited, or Zydus, with respect to the development and sale of certain proprietary products, under which Zydus will focus on developing markets and we will focus on developed markets. Certain terms and conditions of our active agreements with Allergan, Sanofi, Daiichi Sankyo, Roche, Servier, and Aska are summarized below as well as certain terms and conditions of our co-development agreements with Zydus and Stelis.

#### Our agreement with Allergan

In August 2009, we entered into an agreement with Allergan, Inc. (NYSE: AGN) for the use of our proprietary Anticalin technologies in the discovery and development of drug candidates which inhibit a selected target. Under the terms of the agreement, we provided drug candidates for the treatment of ocular diseases, and Allergan is responsible for the further development and commercialization of products based on those candidates and bearing related costs. We have granted Allergan a worldwide and exclusive license under our patent portfolio for the use of certain drug candidates for the treatment and prevention of ocular diseases.

Upon entering into the agreement, we received a payment of \$10 million. We are entitled to receive up to an aggregate of \$13 million in additional payments on achieving various milestones. We are not entitled to any royalties from sales of products commercialized under our agreement with Allergan. During the term of the agreement and as long as Allergan commercializes the drug candidates designated under the agreement, we may not grant rights to any third party with respect to any drug candidates that inhibit the same target within the field licensed to Allergan.

The agreement will remain in effect until the expiration of the payment obligations of Allergan to us thereunder. Either we or Allergan may terminate the agreement in the event of the other party's material breach of the

agreement remains uncured for a specified period or in the event the bankruptcy of the other party. Allergan has the unilateral right to terminate the agreement upon specified prior written notice to us. On termination, all rights granted to Allergan in our Anticalin technologies would end.

#### Our collaboration with Sanofi

In September 2010, we entered into a collaboration and license agreement with Sanofi, which was subsequently amended in February 2013. Under the terms of the agreement, we have agreed to use our proprietary Anticalin technologies to identify drug candidates against certain targets, with further development and commercialization activities conducted by Sanofi. The collaboration started with two targets under two separate collaboration projects and was extended by an additional multispecific Anticalin program in 2013. When we entered the collaboration, we granted Sanofi an exclusive worldwide license to develop drug candidates identified in the course of the collaboration and market products based on those drug candidates under the collaboration.

In consideration of our obligations, as a part of the collaboration we received a  $\notin 3.5$  million (\$3.8 million) upfront payment and specified research funding. We also are entitled to receive payments on the achievement of research, development and commercial milestones for each product, with up to  $\notin 26.5$  million (\$27.9 million) in development milestones and up to  $\notin 18$  million (\$18.9 million) in commercial milestones for the first therapeutic application and lesser amounts on subsequent therapeutic applications. We have the ability to receive over  $\notin 50$  million (\$52.6 million) potential milestone payments from the active collaboration project, including estimated milestone payments in connection with one or more subsequent applications. Payments due to us also include tiered mid-to mid-high single digit royalties on sales of products. We have agreed that we will not use our Anticalin technologies to perform, on our own behalf or for third parties, any research or development activities on the same target to which any active program relates. Unless earlier terminated, the agreement will remain in effect until the expiration of all payment and related obligations of Sanofi thereunder.

During the term of the agreement, Sanofi may terminate any or all programs thereunder for convenience by giving specified prior written notice to us. Either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach or for the other party's insolvency. If a program or the agreement is terminated by Sanofi, rights in products and developed technology resulting from the terminated program (including the right to grant sublicenses) revert or are transferred to us. If a program is terminated prior to the development of the product by Sanofi, our right to commercialize that product is royalty-free. Otherwise, we would owe to Sanofi royalties in the single digits as a percentage of net sales on such product sold by us or our licensee, with total royalty payments capped at a certain amount, and with the royalty rate dependent on the maturity of the program at the time of termination. Sanofi has terminated two of the three programs (one program was terminated for internal strategic reasons and the other program was terminated following *in vivo* studies, as *in vitro* functionality did not fully translate into *in vivo* functionality for this first in class program), and we have the right to develop and commercialize drug candidates of the terminated programs on a royalty-free basis. The remaining active collaboration project was handed over to Sanofi for further development in the fourth quarter of 2014. Additionally, in January 2015, we transferred ownership of the intellectual property of the remaining active collaboration project to Sanofi, including the obligation for payment of expenses of obtaining patents or other registrations of such intellectual property. All other rights and obligations of the parties under the Sanofi collaboration remain unchanged.

### Our collaboration with Daiichi Sankyo

In May 2011, we entered into a definitive collaboration research and technology licensing agreement with Daiichi Sankyo, under which we agreed to use our proprietary Anticalin<sup>®</sup> scaffold technologies to discover novel drug candidates against two targets chosen by Daiichi Sankyo under two separate collaboration projects. Upon achievement of preclinical development milestones for lead drug candidates, Daiichi Sankyo assumes responsibility for, and to use commercially reasonable efforts in, the further development and marketing of products based on those candidates. We handed over further development responsibility for the two collaboration projects to Daiichi Sankyo in March 2013 and June 2014, respectively.

We received  $\notin 7.2$  million (\$7.9 million) upon signing of the collaboration agreement and received research funding. We are entitled to payment on the achievement of research and development milestones of up to  $\notin 35.9$  million (\$37.7 million) for the first prophylactic or therapeutic product, with reduced amounts for achievement of those milestones in additional indications. We are also entitled to payment of commercialization milestones of up to  $\notin 45$  million (\$47.3 million) for a prophylactic or therapeutic product. On development and commercialization of a diagnostic product, we are entitled to development and commercialization milestones of up to  $\notin 45$  million (\$47.3 million) for a prophylactic or therapeutic product. On development and commercialization of a diagnostic product, we are entitled to development and commercialization milestones of up to approximately  $\notin 0.7$  million (\$0.7 million). We have the ability to receive up to approximately  $\notin 200$  million (\$210 million) in potential milestone payments from the two collaboration projects, including estimated milestone payments in connection with one or more additional indications. Daiichi Sankyo is further obliged to pay to us tiered, mid- to mid-high single digit royalties on sales of products for prophylactic and therapeutic uses and low single digits on sales of products for diagnostic uses. We granted Daiichi Sankyo exclusive license rights worldwide for prophylactic and therapeutic products, and nonexclusive rights for diagnostic uses. During the collaboration, we may not use our Anticalin<sup>®</sup> technologies in research or commercial activities on the designated targets for our own account or with third parties.

Daiichi Sankyo may terminate any program under the collaboration after a certain research stage for convenience by giving specified prior written notice to us. Either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach or for the other party's insolvency. If a program is terminated, rights in products and developed technology resulting from the terminated program (including the right to grant sublicenses) revert or are transferred to us. If we terminate a program because of a material breach by Daiichi Sankyo, our sale of products resulting from the program is royalty-free. If a program is terminated by us because of Daiichi Sankyo's failure to meet diligence obligations or by Daiichi Sankyo for convenience, we will be required to pay to Daiichi Sankyo royalties on sale of products resulting from the program in the low single digits as a percentage of net sales up to a specified aggregate royalty amount.

Unless earlier terminated, the agreement will remain in effect until (i) the expiration of all payment and related obligations of Daiichi Sankyo thereunder or (ii) upon the decision of Daiichi Sankyo not to develop any drug candidate under the collaboration agreement.

#### Our collaboration with Roche

On December 8, 2015, Pieris entered into a Research Collaboration and License Agreement with F.Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., collectively Roche, in cancer immune therapy for the research, development and commercialization of Anticalin-based drug candidates against a predefined, undisclosed target.

Under the terms of the agreement, we received an upfront payment of CHF 6.5 million (\$6.5 million) in January 2016 and Roche committed to provide research funding, and we may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid-single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total payments to us could surpass CHF 415 million (\$415.7 million), excluding royalties.

The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalins that bind to a specific target for an expected period of 20 months, which may be extended under certain circumstances. During the research term of the agreement, Roche will fund the work to be performed by us pursuant to the research plan. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product and will have worldwide commercialization rights.

Unless earlier terminated, the term of the agreement continues until no royalty or other payment obligations are or will become due under the agreement. The agreement may be terminated (i) by either party based on insolvency or breach by the other party and such insolvency proceeding is not dismissed or such breach is not cured within 90 days; or (ii) after 15 months from the effective date of the agreement, by Roche as a whole or on a product-by-product and/or country-by-country basis upon 90 days prior written notice before the first commercial sale of a product or upon 180 days prior written notice after the first commercial sale of a product.

Roche may also, in its sole discretion, terminate the agreement upon a change of control of Pieris involving a company that develops or commercializes biopharmaceutical products.

#### Our collaboration with Servier

On January 4, 2017, we, along with Pieris GmbH, entered into a license and collaboration agreement and a non-exclusive license agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier, collectively Servier. Pursuant to the terms of the agreements, we, along with Servier, will initially pursue five bispecific therapeutic programs, led by our PRS-332 program. We will jointly develop PRS-332 and split commercial rights geographically, with Pieris retaining all commercial rights in the U.S. and Servier having commercial rights in the rest of the world. The four additional committed programs, which have been defined, may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on our proprietary platform to generate innovative immuno-oncology bispecific drug candidates. The collaboration may be expanded by up to three additional therapeutic programs. We also have the option to co-develop and retain commercial rights in the U.S. for up to three programs beyond PRS-332, while Servier will be responsible for development and commercialization of the other programs worldwide.

Under the agreements, we received an upfront payment of EUR30 million (approximately 31.3 million USD). We may also receive funding for full time staff for specific projects, as well as development-dependent and commercial milestone payments for PRS-332 and each additional program. The total development, regulatory and sales-based milestone payments to us could exceed EUR1.7 billion (approximately 1.8 billion USD) over the life of the collaboration and are dependent on the final number of projects pursued and the number of co-development options exercised by us. We will share preclinical and clinical development costs for each co-developed program with Servier. In addition, we will be entitled to receive tiered royalties up to low double digits on the sales of commercialized products in the Servier territories.

The term of each agreement ends upon the expiration of all of Servier's payment obligations under such agreement. The agreements may be terminated by Servier for convenience beginning 12 months after their effective date upon 180 days' notice. The agreements may also be terminated by either of us for material breach upon 90 days' or 120 days' notice of a material breach, with respect to the collaboration agreement and license agreement, respectively, provided that the applicable party has not cured such breach by the applicable 90-day or 120-day permitted cure period, and dispute resolution procedures specified in the applicable Agreement have been followed. The agreements may also be terminated due to the other party's insolvency or for a safety issue and may in certain instances be terminated on a product-by-product and/or country-by-country basis. The license agreement will terminate upon termination of the collaboration agreement, on a product-by-product and/or country-by-country basis.

#### Collaboration with Aska

On February 27, 2017, we entered into an Exclusive Option Agreement with ASKA Pharmaceutical Co., Ltd., or Aska, granting Aska an exclusive option to license development and commercial rights to Pieris' anemia drug, PRS-080, in Japan and certain other Asian markets following completion of a multi-dose Phase 2a study to be conducted by Pieris in dialysis-dependent anemia patients.

Under the terms of the option agreement, we received an option payment of \$2.75 million from ASKA. Following an analysis period after the completion of the planned Phase 2a study conducted by Pieris, ASKA may exercise its option to obtain an exclusive license to develop and commercialize PRS-080 in Japan, South Korea and certain other Asian markets (excluding China). Should ASKA exercise the option, we would be eligible for more than \$80 million in combined option exercise fee and milestones associated with development and commercialization of PRS-080 in the first indication in Japan. We may receive further development milestones in additional indications, as well as in other countries within the ASKA territory. We may also receive double-digit royalties on net sales of PRS-080 up to the mid- to high-teens.

The term of the Exclusive Option Agreement, including the option rights granted therein, ends on the earlier of (i) ASKA's written notice to us of ASKA's decision not to exercise the option rights granted under the Exclusive Option Agreement, (ii) ASKA's failure to exercise its option rights within sixty (60) days after the final results of the Phase 2a study are made available to ASKA, (iii) three (3) months from date on which we deliver to ASKA the final results of the Phase 2a study in the European Union, or (iv) our and ASKA's execution of the definitive agreements granting ASKA licenses to develop and commercialize PRS-080 in the Japan, South Korea and certain other Asian countries as contemplated under the Exclusive Option Agreement.

### **TUM License Agreement**

On July 4, 2003, we entered into a Research and Licensing agreement with TUM, which was subsequently renewed and amended, on July 26, 2007. The agreement established a joint research effort led by Prof. Arne Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin scaffolds. We provided certain funding for TUM research efforts performed under the agreement. The research phase of this collaboration ended on February 28, 2013.

Under the terms of the agreement, TUM assigned to us certain materials and records resulting from the research. We retained rights to inventions made by our employees, and TUM assigned to us all inventions made under the agreement jointly by our employees and TUM personnel, provided that our employees made certain inventive contributions. With respect to all other inventions made in the course of the research, TUM granted to us worldwide exclusive license rights under patents and patent applications claiming such inventions. TUM retained rights to practice these inventions for research and teaching purposes.

As a result of research efforts to date under the agreement, we hold a worldwide exclusive license under our license agreement with TUM to multiple patents and patent applications. In the United States, we hold an exclusive license to an issued U.S. patent No. 8,598,317 for the composition of matter of mutein of human tear lipocalin binding to the extracellular region of the T-cell co-receptor CD4 with detectable affinity, which patent will expire in 2027 (subject to a patent term adjustment period which is expected to be at least 742 days), as well as to its counterpart in the European Union. We also hold an exclusive license to an issued U.S. patent No. 8,420,051 directed to library of hNGAL scaffold of certain consensus sequence, which patent is expected to expire in 2029 (subject to a patent term adjustment period of 109 days), as well as to its counterparts in the European Union and in a number of foreign jurisdictions. Moreover, we hold an exclusive license to an issued U.S. patent No. 8,987,415 claiming isolated crystalline form of monomeric bacterial lipocalin. We bear the costs of filing, prosecution and maintenance of patents assigned or licensed to us under the agreement.

As consideration for the assignments and licenses, we are obliged to pay to TUM milestone payments on development of our proprietary products claimed by patents assigned or licensed to us by TUM. For each of such proprietary products developed by us, we could be required to pay up to an aggregate of approximately  $\notin 0.2$  million (\$ 0.2 million) in milestone payments to TUM under the agreement.

We also are obliged to pay low single digit royalties, including annual minimum royalties, on sales of such products. Should we grant licenses or sublicenses to those patents to third parties, we are obliged to share a percentage of resulting revenue with TUM, which percentage of resulting revenue is creditable against our annual license payments to TUM. Our payment obligations are reduced by our proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement.

We can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate our rights in patents assigned to us.

### **Enumeral License Agreement**

On April 18, 2016, we entered into a License Agreement with Enumeral Biomedical Holdings, Inc., or Enumeral, pursuant to which we acquired a non-exclusive (except in the exclusive field described below) worldwide license to use specified patent rights and know-how owned by Enumeral to research, develop and market fusion proteins consisting of PD-1 antibodies linked to one or more Anticalin proteins for use in the oncology area. Enumeral also agreed not to practice or assist third parties in practicing in the exclusive field, consisting of licensed antibodies fused to Anticalin proteins in the oncology area.

On June 6, 2016, we entered into a Definitive License Agreement to fully set forth the terms of Enumeral's license of PD-1 antibodies and grant of options to license additional antibodies to us. Under the Definitive License and Transfer Agreement, we in-licensed intellectual property related to an Enumeral-generated antibody against PD-1 and an option to in-license up to two additional antibodies against undisclosed targets. Under the terms of the agreement, we acquired a non-exclusive worldwide license under the applicable Enumeral patents and know-how to research, develop and commercialize fusion proteins incorporating Enumeral's PD-1 antibody and one or more Anticalin proteins, or the Subsequent Options, which was an expansion of the scope of the original License Agreement.

The Subsequent Options expire on May 31, 2017. If we license an additional antibody pursuant to a Subsequent Option, Pieris must pay to Enumeral an additional option exercise payment, and any resulting fusion protein products will be subject to royalties and development and sales milestones in the same amounts applicable to the fusion proteins consisting of an Enumeral's PD-1 antibody linked to one or more Anticalin® proteins. We are also obliged to pay to Enumeral development and sales milestones on development of products incorporating the Enumeral antibody, as well as low to lower-middle single-digit royalties as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that we are required to pay a license fee or royalty to any third party related to the licensed products, our royalty payment obligations to Enumeral are reduced by the amount of such third party fees or payments, up to 50% of the royalty payment for each calendar year due to Enumeral. Payment obligations terminate on a product-by-product and country-by-country basis on the later of ten years from the first commercial sale of a product incorporating the Enumeral antibody or the last to expire, lapse or be abandoned of a claim from the licensed Enumeral patents filed as of the effective date of the agreement that cover the manufacture, use, offer for sale, sale or import of a product incorporating the Enumeral antibody.

The term of the Definitive License Agreement ends upon the expiration of the last to expire patent covered under the license. The Agreement may be terminated by us on 30 days' notice and by Enumeral upon 60 days' notice of a material breach by us (or 30 days with respect to a breach of payment obligations by us), provided that we have not cured such breach and dispute resolution procedures specified in the Definitive License Agreement have been followed.

### **Government Regulation**

#### United States - FDA Process

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries.

#### U.S. Drug Development Process

In the U.S., the Food and Drug Administration, or FDA, regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, or their issuance of warning

letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an Investigational New Drug application, or IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an New Drug Application, NDA or Biologic License Application , or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND, which must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, an Institutional Review Board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. Study subjects must sign an informed consent form before participating in a clinical trial. There are also requirements governing the reporting of on-going clinical trials and clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase I:* The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase II:* This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase III:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.



The FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Post-approval trials are typically referred to as Phase 4 clinical trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. Including prior to submission of an IND, at the end of Phase II, and before an NDA or BLA is submitted. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the End of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA, or an approved letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency.

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an NDA for a new molecular entity and original BLAs will be six months from the date that the NDA or BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical

endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, made permanent the Pediatric Research Equity Act, or PREA, which requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

#### Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension. These patent term extensions permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of fourteen years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. The FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If a Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies.

#### Biologics Price Competition and Innovation Act of 2009

In March 2010, the Patient Protection and Affordable Care Act was enacted in the U.S. and included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the Public Health Service Act, or PHSA, to create an abbreviated approval pathway for two types of "generic" biologics—biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

#### Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical trials to support the approval of drugs, biologics, medical devices, and medical foods for rare diseases and conditions. A product does not have to be designated as an orphan drug to be eligible for the grant program. An application for an orphan grant should propose one discrete clinical study to facilitate FDA approval of the product for a rare disease or condition. The study may address an unapproved new product or an unapproved new use for a product already on the market.

#### Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or lifethreatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.



In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post- approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track drug's BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

#### Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

#### Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 28-member European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

When conducting clinical trials in the EU, we must adhere to the provisions of the EU Clinical Trials Directive and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the submission and approval of a clinical trial authorization application be obtained in each Member State be obtained before commencing a clinical trial in that Member State.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. As in the United States, a sponsor may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

#### Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors include government healthcare programs, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to by significantly lower.

#### Description of the Acquisition

On December 17, 2014, Pieris Pharmaceuticals, Inc., Pieris Pharmaceuticals GmbH ("Pieris GmbH") and the former stockholders of Pieris GmbH entered into an Acquisition Agreement, or the Acquisition Agreement. Pursuant to the Acquisition Agreement, the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH

becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. Prior to the Acquisition, as defined below, Pieris pursued a business of an errand concierge service online marketplace.

Prior to the closing of the Acquisition, on December 5, 2014, Pieris completed a 2.272727-for-1 forward split of its common stock in the form of a share dividend, with the result that 6,100,000 shares of common stock outstanding immediately prior to the stock split became 13,863,647 shares of common stock outstanding immediately thereafter. On December 16, 2014, Pieris amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to "Pieris Pharmaceuticals, Inc.," and increase its authorized capital stock from 75,000,000 shares of common stock, par value \$0.001 per share, to 300,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value \$0.001 per share.

On December 17, 2014, Pieris, Pieris GmbH and the former stockholders of Pieris GmbH entered into an Acquisition Agreement, or the Acquisition Agreement. Pursuant to the Acquisition Agreement, the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. The Acquisition closed on December 17, 2014.

In connection with the Acquisition and pursuant to a Split-Off Agreement, dated December 17, 2014 among Pieris, Marika Enterprises Inc. and Aleksandrs Sviks, or the Split-Off Agreement, and a general release agreement, Pieris transferred its pre-Acquisition assets and liabilities to its former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris common stock, or the Split-Off. Upon the closing of the Acquisition and the Split-Off, Pieris discontinued its pre-Acquisition business plans and is now pursuing only the business of Pieris GmbH.

Upon the closing of the Acquisition, Pieris ceased to be a "shell company" under applicable rules of the SEC. On December 17, 2014, in connection with the Acquisition, our Board of Directors changed our fiscal year from a fiscal year ending on June 30 to one ending on December 31 of each year, which was the fiscal year of Pieris GmbH.

#### Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, establishes a class of company called an "emerging growth company," which generally is a company whose initial public offering was completed after December 8, 2011 and had total annual gross revenues of less than \$1 billion during its most recently completed fiscal year. Additionally, Section 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, establishes a class of company called a "smaller reporting company," which generally is a company with a public float of less than \$75 million as of the last business day of its most recently completed fiscal year for which audited financial statements are available. We currently qualify as both an emerging growth company and a smaller reporting company.

As an emerging growth company and a smaller reporting company, we are eligible to take advantage of certain extended accounting standards and exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including without limitation the following:

• An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.

- An emerging growth company is exempt from 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 financial statements, commonly known as an "auditor discussion and analysis."
- An emerging growth company is not required to hold nonbinding advisory stockholder votes on executive compensation or any "golden parachute" payments not previously approved by stockholders.
- Neither an emerging growth company nor a smaller reporting company is required to comply with the requirement of auditor attestation of internal controls over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act of 2002.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced financial statement disclosure in its registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earlier of (i) December 31, 2019, the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019. We will remain a smaller reporting company until we have a public float of \$75 million or more as of the last business day of our most recently completed second fiscal quarter, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

#### Employees

As of March 23, 2017, we had 49 full-time employees and 3 part-time employees. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. In order to successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring additional employees for research and development, clinical and regulatory affairs and general and administrative activities over the next few years. We also utilize the services of consultants, clinical research organizations, and other third parties on a regular basis.

#### **Available Information**

Our internet address is www.pieris.com. Copies of the our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the Investors section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. We have included our website address in this Annual Report solely as an inactive textual reference.

### Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes, before making any decision to invest in shares of our common stock. This Annual Report on Form 10-Kcontains forward-looking statements. If any of the events discussed in the risk factors below occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

### Risks Related to Our Business, Financial Position and Capital Requirements

#### We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We currently have no product revenues and no approved products, and will need to raise additional capital to operate our business.

We are a clinical-stage biopharmaceutical company. To date, we have not generated any product revenue and are not profitable, and have incurred losses since our inception in August 2000. For the years ended December 31, 2016 and 2015 we reported net loss of \$22.8 million and \$14.1 million, respectively. As of December 31, 2016, we had an accumulated deficit of \$102.7 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates and the commercialization of approved products, if any.

We are currently focused primarily on the development of our lead drug candidates, PRS-080, PRS-060 and our 300-series programs, as well as our other programs, which we believe will result in our continued incurrence of significant research, development and other expenses related to those programs. If preclinical studies or the clinical trials for any of our drug candidates fail or produce unsuccessful results and those drug candidates do not gain regulatory approval, or if any of our drug candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

# We will need substantial additional funding to continue our operations, which could result in significant dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, or on terms acceptable to us, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Our operations have consumed substantial amounts of cash since inception. We expect to need substantial additional funding to pursue the clinical development of our drug candidates, launch, and commercialize any drug candidates for which we receive regulatory approval.

We will require additional capital for the further development and commercialization of our drug candidates and may need to raise additional funds sooner than we currently anticipate if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we advance preclinical development and prepare for potential clinical trials of our 300-Series programs, particularly PRS-343, advance PRS-080 through clinical trials and prepare for a Phase I clinical trial of PRS-060. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to regulatory requirements, product manufacturing, marketing, sales and distribution.



Furthermore, we expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs and/or cause us to spend our cash resources faster than we expect.

To date, we have financed our operations through a mix of equity investments from private and public investors, the incurrence of debt, grant funding, and revenues from our various collaboration agreements, and we expect to continue to finance our operations through equity investments from public investors for the foreseeable future. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all.

If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. If we raise additional capital through the incurrence of indebtedness, we would likely become subject to covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our Anticalin ®-brand technology or drug candidates and could result in our receipt of only a portion of the revenues associated with the partnered drug.

If we are unable to raise capital, when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development for our drug candidates or any future commercialization efforts. Any of these events could significantly harm our business, financial condition, and prospects.

#### Our limited operating history as a clinical stage company may hinder our ability to successfully meet our objectives.

We were formed in August 2000 and, since that time our focus has been on discovery of Anticalin<sup>®</sup>-brand drug candidates. We are currently conducting clinical development of PRS-080, and are continuing preclinical development of PRS-060 with plans to begin initial Phase I trials in the second half of 2017, and PRS-343 with plans to initiate Phase I trials in the second quarter of 2017, as well as other drug candidates, and are also exploring additional indications that may be suitable for Anticalin-brand drug therapeutics, primarily immuno-oncology candidates. Our drug candidates are in early stages of development, have not obtained marketing approval, have never generated any revenue from sales, and will require extensive testing before commercialization. We have limited operating experience with respect to clinical-stage operations and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. In addition, the early-stage nature of our drug development operations can only provide limited operating results upon which you can evaluate our business and prospects.

Our limited operating history may adversely affect our ability to implement our business strategy and achieve our business goals, which include, among others, the following activities:

- developing our drug candidates using unproven technologies;
- undertaking preclinical development and clinical trials as well as formulating and manufacturing products;
- obtaining the human and financial resources necessary to develop, test, manufacture, commercialize and market our drug candidates;
- engaging corporate partners to assist in developing, testing, manufacturing and marketing our drug candidates;



- continuing to build and maintain an intellectual property portfolio covering our technology and our drug candidates;
- satisfying the requirements of clinical trial protocols, including patient enrollment, establishing and demonstrating the clinical safety and efficacy of our drug candidates and obtaining necessary regulatory approvals;
- achieving acceptance and use by the medical community of our drug candidates after they receive regulatory approvals;
- maintaining, growing and managing our internal teams as and to the extent we increase our operations and develop new segments of our business;
- developing and maintaining successful collaboration, strategic and other relationships for the development and commercialization of our drug candidates that receive regulatory approvals with existing and new partners; and
- managing our cash flows and any growth we may experience in an environment where costs and expenses relating to clinical trials, regulatory approvals and commercialization continue to increase.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop drug candidates, raise capital, expand our business or continue our operations.

#### Our global operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations.

Our business is subject to certain risks associated with doing business globally. One of our growth strategies is to pursue opportunities for our business in several areas of the world, both inside and outside of the United States, Germany, Europe and Australia, any or all of which could be adversely affected by the risks set forth below. Accordingly, we face significant operational risks as a result of doing business internationally, such as:

- fluctuations in foreign currency exchange rates;
- potentially adverse tax consequences;
- challenges in providing solutions across a significant distance, in different languages and among different cultures;
- different, complex and changing laws governing intellectual property rights, sometimes affording reduced protection of intellectual property rights in certain countries;
- difficulties in staffing and managing foreign operations, particularly in new geographic locations;
- · restrictions imposed by local labor practices and laws on our business and operations;
- rapid changes in government, economic and political policies and conditions, political or civil unrest or instability, terrorism or epidemics and other similar outbreaks or events;
- compliance with a wide variety of complex foreign laws, treaties and regulations;
- tariffs, trade barriers and other regulatory or contractual limitations on our ability to develop or sell our products in certain foreign markets; and
- becoming subject to the laws, regulations and court systems of multiple jurisdictions.

Our failure to manage the market and operational risks associated with our international operations effectively could limit the future growth of our business and adversely affect our results of operations.

#### Our international operations pose currency risks, which may adversely affect our operating results and net income.

Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. Our reporting currency is the U.S. dollar, however, 70% of our operating

expenses and all of our revenues come from operations outside of the United States. As such, the financial statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year and (3) stockholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in stockholders' equity.

As we realize upon our strategy to expand internationally, our exposure to currency risks will increase. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies and the U.S. dollar will affect our revenues and expenses and could result in exchange losses in any given reporting period.

We incur currency transaction risks whenever we enter into either a purchase or a sale transaction using a different currency other than the U.S. dollar, our functional currency, in particular our arrangements for the purchase of supplies or licensing and collaboration agreements with partners outside of the United States. In such cases, we may suffer an exchange loss because we do not currently engage in currency swaps or other currency hedging strategies to address this risk.

Given the volatility of exchange rates, we can give no assurance that we will be able to effectively manage our currency transaction risks or that any volatility in currency exchange rates will not have an adverse effect on our results of operations.

# If we fail to comply with environmental, health and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of any hazardous materials we use and wastes we produce. The use of these materials in our business could result in contamination or injury, which could cause damage for which we may be responsible but may not have sufficient resources to pay. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with these laws and regulations, which we may not be able to afford.

Although we maintain workers' compensation insurance for our operations in Germany to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations applicable to us. These current or future laws and regulations may impair our research, development or production efforts or impact the research activities we pursue, particularly with respect to research involving human subjects or animal testing. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could cause our financial condition to suffer.

# Health and safety regulations in the United States, Germany, and Australia and in the countries where our technology and potential products are licensed or sold may prevent the sale or use of our technology or products in the future.

We are subject to a variety of regulations regarding worker health and safety in the United States, Germany, Australia, and in the countries where our technology and potential products are licensed or sold. Because our technology and potential products may frequently involve the manufacture or use of certain chemical or



biological compounds, we are required to certify their safety for industrial use and development in a variety of countries and contexts. As there has not been sufficient testing to determine the long-term health and environmental risks of all of the materials used in the production of Anticalin drug candidates and any future products, future regulations may ban the use of our products due to the potential risk they pose to workers or may limit the use of our drug candidates in research and commercial settings. Any such regulations may have a substantial negative impact on our business and revenues, and may cause our business to fail. Because we cannot guarantee the long-term safety of use or exposure to materials used during development or manufacture of our products, we may face liability for health risks or harms caused as a result of developing, manufacturing or other processes that use such materials. Any such claims may have a negative impact on our revenues and may prove substantially disruptive to our business in the future.

In addition, under the European Union regulation on classification, labeling and packaging of substances and mixtures, or CLP, we may be required to publicly disclose the composition of our proprietary products or substances, which may facilitate infringement or avoidance of our intellectual property by third parties and may potentially reduce the margin we are able to charge for our products by allowing competitors to more accurately determine our production costs. Future development of the CLP regulation may have a further negative impact our revenues and a substantial negative impact on our business.

#### We may be limited in our use of our net operating loss carryforwards.

As of December 31, 2016, the Company had net operating loss carryforwards for United States federal income tax purposes of \$12.9 million and net operating loss carryforwards for state income tax purposes of \$9.8 million. These tax loss carryforwards expire through 2036. In the United States, utilization of the NOL carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income and tax, respectively. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected.

As of December 31, 2016, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately \$66.3 million and \$64.9 million, respectively, which may be used to reduce our future taxable income in our German jurisdiction. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) \$1,051,550 plus 60% of the exceeding taxable income and trade profit of such period. In addition, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity.

The Company revised the carrying value as of December 31, 2015 of its deferred tax asset for net operating loss carryforwards in foreign jurisdictions by \$8.9 million. The increase in the deferred tax asset was offset by a corresponding increase in the Company's valuation allowance. This adjustment is to accurately reflect the value of net operating losses that the Company believes it is entitled to benefit from to offset future income, if any, in foreign jurisdictions. In addition, the Company recorded an uncertain tax position, that if successfully challenged by tax authorities could result in the loss of certain tax attributes. The balance of uncertain tax positions will remain until such time that settlement is reached with the relevant tax authorities or should the statute of limitations expire.

# Our business and operations would suffer in the event of system failures, and our operations are vulnerable to interruption by natural disasters, terrorist activity, power loss and other events beyond our control, the occurrence of which could materially harm our business.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access as well as telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to

date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our drug candidates could be delayed.

We are also vulnerable to accidents, electrical blackouts, labor strikes, terrorist activities, war and natural disasters and other events beyond our control, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such events and do not have an applicable recovery plan in place. Except for our operations in Germany, where we have business interruption insurance against losses or damages resulting from fire, we do not carry other business interruption insurance that would compensate us for actual losses from interruptions of our business that may occur, and any losses or damages incurred by us could cause our business to materially suffer.

#### There could be an adverse change or increase in the laws and/or regulations governing our business.

We are subject to various laws and regulations in different jurisdictions, and the interpretation and enforcement of laws and regulations are subject to change. We are also subject to different tax regulations in each of the jurisdictions where we conduct our business or where our management is located. We expect the scope and extent of regulation in the jurisdictions in which we conduct our business, or where our management is located, as well as regulatory oversight and supervision, to generally continue to increase. There can be no assurance that future regulatory, judicial and legislative changes in any jurisdiction will not have a material adverse effect on us or hinder us in the operation of its business.

#### Risks Related to the Discovery and Development of Our Drug Candidates

# We are heavily dependent on the successful development of our drug candidates and programs and we cannot be certain that we will receive regulatory approvals or be able to successfully commercialize our products even if we receive regulatory approvals.

We currently have no products that are approved for commercial sale. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead drug candidates, our 300-Series programs, particularly PRS-343, PRS-080, PRS-060, as well as our other programs. We completed dosing of healthy volunteers in a Phase Ia clinical trial with PRS-080 in June 2015 and initiated a Phase Ib clinical trial in the first quarter of 2016; PRS-060 is in preclinical development with Phase I trials expected to begin in the second half of 2017. We are also conducting preclinical experiments on a number of 300-Series lead candidates, including PRS343, which is currently undergoing IND-enabling activities with Phase I trials expected to begin in the second quarter of 2017. All of our other drug candidates are in the discovery or early preclinical stage. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of PRS-080, PRS-060 and our 300-Series programs, which may never occur.

Before we can generate any revenues from sales of our lead drug candidates, we must complete the following activities for each of them, any one of which we may not be able to successfully complete:

- conduct additional preclinical and clinical development;
- manage preclinical, manufacturing and clinical activities;
- obtain regulatory approval;
- establish manufacturing relationships for the clinical supply of the applicable drug candidate;
- build a commercial sales and marketing team, either internally or by contract with third parties;



- · develop and implement marketing strategies; and
- invest significant additional cash in each of the above activities.

Clinical testing of PRS-060 and our 300-Series programs, including PRS-343, has not yet commenced, and the results of any future preclinical studies or clinical trials of PRS-060 and our 300-Series programs, if unsuccessful, could lead to our abandonment of the development of those drug candidates as well. If studies of these drug candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed.

# Preclinical and clinical testing of our drug candidates that have been conducted to date or will be conducted in future may not have been or may not be performed in compliance with applicable regulatory requirements, which could lead to increased costs or material delays for their further development.

Given the complexity as well as the uncertainty inherent in biopharmaceutical preclinical studies and clinical trials, and because of our limited operating experience, we may discover that our own development activities have not been or are not in compliance with applicable regulatory requirements or have otherwise been or are deficient, and, therefore, advancement of the development of the drug candidates on the basis of those trials and studies is not warranted or will be delayed.

We have also entered into license and partnership arrangements, such as with Allergan Inc., or Allergan, Daiichi Sankyo Company Limited, or Daiichi Sankyo, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA), or Sanofi, Cadila Healthcare Limited (Zydus Cadila), or Zydus, Strides Arcolab Limited, or Stelis, F.Hoffmann—La Roche Ltd., or Roche, Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier and Aska Pharmaceuticals Co., Ltd., or ASKA, relating to certain of our drug candidates, and may continue to do so in the future. Under certain of such arrangements, the development of those drug candidates has been, or in the future may be, conducted wholly by such partners or any third parties with which the partners contract. As a result, we have not been or may not be closely involved with or have any control over those development activities. Although certain of such partners have provided information regarding those drug candidates and the related preclinical studies conducted to date, including certain data that is included in this Annual Report on Form 10-K, we have not received and do not yet have access to comprehensive information regarding those development activities, including the raw data from the studies that have been conducted, information regarding the design, procedural implementation and structure and information regarding the manufacture of the drug candidates used in the studies. Because we have had no input on the development to date of these drug candidates, we may discover that all or certain elements of the trials and studies our partners have performed have not been, or may not in the future be, in compliance with applicable regulatory standards or have otherwise been or may be deficient, and that advancement of the development of these drug candidates on the basis of those trials and studies is not warranted.

Further, the majority of our development activities for each of our drug candidates to date, including our Phase I clinical trial with PRS-080 in healthy volunteers, which was conducted in Germany and our anticipated future clinical trials, have been or are being conducted outside the United States, primarily in Europe as well as in Australia, and we may conduct some of our future development activities in other countries or regions. As a result, although those studies may meet the standards of certain applicable foreign regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable U.S. Food and Drug Administration, or FDA, standards to allow immediate further development of those drug candidates in the United States, and also may not meet the standards of the applicable regulatory authorities in foreign countries in which we desire to pursue marketing approval for these drug candidates.

If the studies conducted by us or our partners or collaborators have not been in full compliance with applicable regulatory requirements or are otherwise not eligible for continued development in the United States, then we or our partners may be forced to conduct new studies in order to progress the development of our drug candidates. We, or our partners, may not have the funding or other resources to conduct or complete these new studies,

which would severely delay the development plans for these drug candidates and their commercialization. Any such deficiency and delay in the development of these drug candidates would significantly harm our business plans, product revenues and prospects.

# Our research and development is based on a rapidly evolving area of science, and our approach to drug discovery and development is novel and may never lead to marketable products.

Biopharmaceutical product development is generally a highly speculative undertaking and by its nature involves a substantial degree of risk. Our specific line of business, the discovery of Anticalin-brand drug therapeutics for patients with a variety of diseases and conditions, such as anemia, asthma and cancer, is an emerging field, and the scientific discoveries that form the basis for our efforts to develop drug candidates are relatively new. Further, the scientific evidence to support the feasibility of developing drug candidates based on those discoveries is both preliminary and limited. In contrast with companies who focus on more traditional drug classes, such as antibodies and small molecules, we believe we are the first, if not the only company, to work with Anticalin-brand drug therapeutics and work to advance these to a clinical stage of development. We are not aware of any company that has successfully developed and obtained approval for a drug based on Anticalin proteins. As a result, identifying drug targets based in part on their suitability with Anticalin-brand drug therapeutics, which is a fundamental aspect of our business approach, may not lead to the discovery or development of any drugs that successfully treat patients with the diseases and conditions we intend to target. Moreover, the lack of successful precedents in the development of Anticalin proteins could result in added complexities or delays in our development efforts. The failure of the scientific underpinnings of our business model to produce viable drug candidates would substantially harm our operations and prospects.

#### We may not be successful in our efforts to build a pipeline of drug candidates.

A key element of our strategy is to use and expand our Anticalin drug platform to build a pipeline of drug candidates to address different targets, and progress those drug candidates through clinical development for the treatment of a variety of different types of diseases. Although our research efforts to date have resulted in identification of a series of targets, we may not be able to develop drug candidates that are safe and effective inhibitors or promoters of all or any of these targets. Even if we are successful in building a product pipeline, the potential drug candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential drug candidates fail to produce a pipeline of potentially viable drug candidates, then our success as a business will be dependent on the success of fewer potential drug candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

# Clinical drug development involves a lengthy and expensive process with uncertain outcomes, is very difficult to design and implement, and any of our clinical trials could produce unsuccessful results or fail at any stage in the process.

Clinical trials conducted on humans are expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Additionally, any positive results of preclinical studies and early clinical trials of a drug candidate may not be predictive of the results of later-stage clinical trials, such that drug candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier phases of the trials. Therefore, the results of any ongoing or future clinical trials we conduct may not be successful.

We completed dosing of healthy volunteers in the clinical Phase Ia trial for PRS-080 in June 2015 and initiated a Phase Ib trial in the first quarter of 2016, and are planning to initiate clinical trials for PRS-060 and PRS 343 in



2017. We may however experience delays in pursuing those or any other clinical trials, and any planned clinical trials may not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner, and may not be completed on schedule, if at all.

Clinical trials may be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each trial site;
- enrolling suitable volunteers or patients to participate in a trial;
- developing and validating companion diagnostics on a timely basis;
- changes in dosing or administration regimens;
- having patients complete a trial or return for post-treatment follow-up;
- inability to monitor patients adequately during or after treatment;
- clinical investigators deviating from trial protocols or dropping out of a trial;
- regulators instituting a clinical hold due to observed safety findings or other reasons;
- adding new or substituting clinical trial sites; and
- · manufacturing sufficient quantities of drug candidate for use in clinical trials.

We rely and plan to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have and expect that we will have agreements in place with CROs governing their committed activities and conduct, we will have limited influence over their actual performance. As a result, we ultimately do not and will not have control over a CRO's compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements, or its adherence to agreed time schedules and deadlines, and a future CRO's failure to perform those obligations could subject any of our clinical trials to delays or failure.

Further, we may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or Ethics Committee at an institution in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for the trial, if applicable, or by the FDA, the European Medicines Agency, or EMA, or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Therefore, we cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

If we experience delays in the commencement or completion of, or suspension or termination of, any clinical trial for our drug candidates, the commercial prospects of the drug candidate could be harmed, and our ability to generate product revenues from the drug candidate may be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize regulatory approval of our drug candidates and our ability to commence sales and generate revenues. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects significantly.

# If we experience delays or difficulties in the enrollment of research subjects in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of research subjects to participate in these trials. In particular, for some diseases and conditions we are or will be focused on, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and volunteers or patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation:

- the severity of the disease under investigation;
- the frequency of the molecular alteration we are seeking to target in the applicable trial;
- the eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the drug candidate under the clinical trial;
- the extent of the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- · the ability to monitor volunteers or patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of the trial.

# The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our drug candidates from applicable regulatory authorities, we will not be able to market and sell those drug candidates in those countries or regions and our business could be substantially harmed.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our drug candidates in the United States until we receive the respective approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain approval, if any, by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. We have not submitted a BLA or similar filing (such as marketing authorization, or MA, from the EMA for commercial sale in the European Union) or obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval for many reasons, including any one or more of the following:

• the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;



- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, PRS-080, PRS-060, our 300-series programs, our discovery stage programs, or any other drug candidates we may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs.

In order to market and sell our products in any jurisdiction, we or our third party collaborators must obtain separate marketing approvals in that jurisdiction and comply with its regulatory requirements. The review and approval procedures can vary drastically among jurisdictions, and each jurisdiction may impose different testing and other requirements to obtain and maintain marketing approval. Further, the time required to obtain those approvals, if any, may differ substantially among jurisdictions. In addition, in many countries or regions outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country or region. Moreover, approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or regions. As a result, the ability to market and sell a drug candidate in more than one jurisdiction can involve significant additional time, expense and effort, and would subject us and our collaborators to the numerous and varying post-approval requirements of each jurisdiction governing commercial sales, manufacturing, pricing and distribution of our drug candidates. We or any third parties with whom we may collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for our drug candidates in foreign jurisdictions could severely limit their potential market and ability to generate revenue.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates.



# We may expend our limited resources to pursue a particular drug candidate or indication that does not produce any commercially viable products and may fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus our efforts on particular research programs and drug candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Further, our resource allocation decisions may result in our use of funds for research and development programs and drug candidates for specific indications that may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Any such failure to improperly assess potential drug candidates could result in missed opportunities and/or our focus on drug candidates with low market potential, which would harm our business and financial condition.

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

# We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for our drug candidates and our business could be substantially harmed.

We depend upon independent investigators and contractors, such as CROs, universities and medical institutions, to conduct our preclinical studies and clinical trials. We rely upon, and plan to continue to rely upon, such third-party entities to execute our preclinical studies and clinical trials and to monitor and manage data produced by and relating to those studies and trials. However, we may not be able to in the future establish arrangements with CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug candidates and materially harm our business, operations and prospects. As a result of the use of third-party contractors, we will have only limited control over certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies, including each of our clinical trials, is conducted in accordance with the applicable protocol, legal and regulatory requirements as well as scientific standards, and our reliance on any third-party entity will not relieve us of our regulatory responsibilities.

Based on our present expectations, we and our third-party contractors will be required to comply with current Good Clinical Practice, or cGCP, for all of our drug candidates in clinical development. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our contractors fail to comply with applicable cGCP, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a drug candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from any sales of such drug candidate. Any agreements governing our relationships with outside contractors such as CROs, or CROs or other contractors we may engage in the future, may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances. If such an outside contractor terminates its relationship with us during the performance of a clinical trial, we would be forced to seek an engagement with a substitute contractor, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and the applicable clinical trial would experience delays or may not be completed.

If our contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to a failure to adhere to our clinical protocols, legal and regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully



commercialize, the affected drug candidates. In addition, we will be unable to control whether or not they devote sufficient time and resources to our preclinical and clinical programs. These outside contractors may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. As a result, our operations and the commercial prospects for the effected drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. These contractors may also have relationships with other commercial entities, some of whom may compete with us. If our contractors assist our competitors to our detriment, our competitive position would be harmed.

We rely and expect to continue to rely completely on third parties to formulate and manufacture our preclinical, clinical trial and postapproval drug supplies. The development and commercialization of any of our drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such drug supplies or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements or contractual obligations and our operations could be harmed as a result.

We have no experience in drug formulation or manufacturing. We do not currently have, nor do we plan to acquire, the infrastructure or capability internally, such as our own manufacturing facilities, to manufacture our preclinical and clinical drug supplies for use in the conduct of our preclinical studies and clinical trials or commercial quantities of any drug candidates that may obtain regulatory approval. Therefore, we lack the resources and expertise to formulate or manufacture our own drug candidates. We have entered into agreements with third-party manufacture contractors, or CMOs, for the clinical-stage manufacture of certain of our drug candidates, including PRS-080. We plan to enter into agreements with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our current and future clinical trials and/or commercial sales. We intend to establish or continue those relationships for the supply of our drug candidates, however, there can be no assurance that we will be able to retain those relationships on commercially reasonable terms, if at all. If we are unable to maintain those relationships, we could experience delays in our development efforts as we locate and qualify new CMOs. If any of our current drug candidates or any drug candidates we may develop or acquire in the future receive regulatory approval, we will rely on one or more CMOs to manufacture the commercial supply of such drugs.

Our reliance on a limited number of CMOs exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited Following BLA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for the production of our products after their receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as contractually agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, regulations and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our drug candidates by the FDA or the commercialization of our drug candidates or result in higher costs or deprive us of potential product revenues.



We expect to have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute contract manufacturer that can comply with such requirements, which we may not be able to do. Any such failure by any of our contract manufacturers would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Further, we plan to rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our drug candidates for our clinical trials. We do not have, nor do we expect to enter into, any agreements for the commercial production of these raw materials, and we do not expect to have any control over the process or timing of our contract manufacturers' acquisition of raw materials needed to produce our drug candidates. Any significant delay in the supply of a drug candidate or the raw material components thereof for an ongoing clinical trial due to a manufacturer's need to replace a third-party supplier of raw materials could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates. Additionally, if our future manufacturers or we are unable to purchase these raw materials to commercially produce any of our drug candidates that gains regulatory approvals, the commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.

# Disagreements with respect to the commercial terms of our sales, licensing, purchase or manufacturing agreements may limit our commercial success.

The rights and obligations of the partners to which we may license our Anticalin technology are governed by the licensing and collaboration agreements we enter into with those partners. In addition, our relationships with CROs and CMOs are governed by the service agreements between us and each manufacturer. Although we attempt to address the full range of possible events that may occur during the development or the manufacturing of Anticalin drug candidates and products, unanticipated or extraordinary events may occur beyond those contemplated by said agreements. Furthermore, our business relationships with our product manufacturers and our collaborators may include assumptions, understandings or agreements that are not included in our agreements with them, or that are inaccurately or incompletely represented by their terms. In addition, key terms in such agreements may be misunderstood or contested, even when both we and the other party previously believed that we had a mutual understanding of our obligations.

Any differences in interpretation or misunderstandings between us and other parties may result in substantial costs and delays with respect to the development, manufacturing or sale of Anticalin drugs, and may negatively impact our revenues and operating results. Product manufacturers may fail to produce the products and partners may fail to develop the drug candidates under the timeline or in the manner we anticipated, and results may differ from the terms upon which we had agreed. As a result, we may be unable to supply drugs of the quality or in the quantity demanded or required. We may suffer harm to our reputation in the market from missed development goals or deadlines, and may be unable to capitalize upon market opportunities as a result. Resolution of these problems may entail costly and lengthy litigation or dispute resolution procedures. In addition, there is no guarantee that we will prevail in any such dispute or, if we do prevail, that any remedy we receive, whether legal or otherwise, will adequately redress the harm we have suffered. The delays and costs associated with such disputes may themselves harm our business and reputation and limit our ability to successfully compete in the market going forward.

# We depend on third parties and intend to continue to license or collaborate with third parties, and events involving these strategic partners or any future collaboration could delay or prevent us from developing or commercializing products.

Our business strategy and our short- and long-term operating results depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. We have entered into and expect in the future to enter into collaborative arrangements with established pharmaceutical companies, which will lead, finance or otherwise collaborate or assist in the development, manufacture and marketing of drug products. We believe collaborations allow us to leverage our resources and technologies and we anticipate deriving some revenues from research and development fees, license fees, milestone payments, and royalties from collaborative partners.

Our prospects, therefore, may depend to some extent upon our ability to attract and retain collaborative partners and to develop technologies and products that meet the requirements of current or prospective collaborative partners. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborative activities successfully and in a timely manner. Further, our collaborators may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. In addition, our collaborative partners may have the right to abandon research projects, guide strategy regarding prosecution of relevant patent applications and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed-upon research terms. By entering into such collaborations, we may preclude opportunities to collaborate with other third parties who do not wish to associate with our existing third party strategic partners. In the event of termination of a collaboration agreement, termination negotiations may result in less favorable terms.

There can be no assurance that we will be successful in establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before completion of projects, that our collaborative arrangements will result in successful product commercialization, or that we will derive any revenues from such arrangements. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Additionally, the negotiation, documentation and implementation of collaborative arrangements are complex and time-consuming. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property filings.

# Our success depends in part on the efforts of our current and possible future collaborators, who will likely have substantial control and discretion over the continued development and commercialization of drug candidates that are the subject of our collaborations.

Our current collaborators and future collaborators will have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations. Our collaborators may determine not to proceed with clinical development or commercialization of a particular drug candidate for a number of reasons that are beyond our control, even under circumstances where we might have continued such a program. In addition, our rights to receive milestone payments and royalties from our collaborators will depend in part on our collaborators' abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates. We may also depend on our collaborators to manufacture clinical scale quantities of some of our drug candidates and, possibly, for commercial scale manufacture, distribution and sales. Our collaborators may not be successful in manufacturing our drug candidates or successfully commercializing them.

We face additional risks in connection with our existing and future collaborations, including the following:

- our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with the products that are the subject of the collaboration with us;
- our collaborators may underfund, not commit sufficient resources to, or conduct in an unsatisfactory manner the development, testing, marketing, distribution or sale of our drug candidates;

- our collaborators may not properly maintain or defend our intellectual property rights or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our intellectual property or proprietary information or expose us to potential liability;
- our collaborators may encounter conflicts of interest, changes in business strategy or other business issues which could adversely
  affect their willingness or ability to fulfill their obligations to us (for example, pharmaceutical and biotechnology companies
  historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in
  these industries);
- disputes may arise between us and our collaborators delaying or terminating the research, development, manufacture or commercialization of our drug candidates, resulting in significant litigation or arbitration that could be time-consuming and expensive, or causing collaborators to act in their own self-interest and not in the interest of our stockholders;
- we might not have the financial or human resources to meet our obligations or take advantage of our rights under the terms of our existing and future collaborations; and
- our existing collaborators may exercise their respective rights to terminate without cause their collaborations with us, in which event, we might not be able to complete development and commercialization of our drug candidates on our own.

### We may not receive any further milestone, royalty or license payments under our current collaborations.

Although we have received upfront, milestone and other payments to date under our current drug development collaborations, we may not receive any royalty payments or additional license and milestone fees under such agreements. In general, our receipt of milestone, royalty or license payments depends on many factors, including whether our collaborators want and are able to continue to pursue potential drug candidates, intellectual property issues, unforeseen complications in the development or commercialization process, and the ultimate commercial success of the drugs.

#### **Risks Related to the Commercialization of Our Drug Candidates**

#### Even if we receive regulatory approval for any of our drug candidates, we will be subject to ongoing regulatory obligations and review. Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the products may be marketed, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines or warning letters;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;

- · product seizure or detention, or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

In addition, regulatory authorities' policies (such as those of the FDA or EMA) may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

# Our commercial success depends upon attaining significant market acceptance of our drug candidates, if approved, among physicians, patients, healthcare payors and other members of the medical community.

Even if we obtain regulatory approval for our drug candidates, the products may not gain market acceptance among physicians, health care payors, patients and other members of the medical community, which is critical to commercial success. Market acceptance of any drug candidate for which we receive approval depends on a number of factors, including:

- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products;
- the size of the markets for the drug candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the potential and perceived advantages of the drug candidate over alternative treatments;
- the safety of the drug candidate as demonstrated through broad commercial distribution;
- the availability of adequate reimbursement and pricing for our products from governmental health programs and other third-party payors;
- · relative convenience and ease of administration;
- cost-effectiveness of our product relative to competing products;
- · the prevalence and severity of adverse effects; and
- the effectiveness of sales, marketing and distribution efforts by us and our licensees and distributors, if any.

If our drug candidates are approved but fail to achieve an adequate level of acceptance by key market participants, we will not be able to generate significant revenues, and we may not become or remain profitable, which may require us to seek additional financing.

# Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for PRS-080 or other product candidates which achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

# Reimbursement may be limited or unavailable in certain market segments for our drug candidates, which could make it difficult for us to sell on a profitable basis any products for which we obtain marketing approvals.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Market acceptance and successful commercialization of any of our drug candidates that obtain regulatory approval in domestic or international markets will depend significantly on the availability of adequate coverage and reimbursement from governmental authorities, private health insurers, and other third-party payors for any of our drug candidates, and may be affected by existing and future healthcare reform measures.

Pricing and reimbursement for any of our drug candidates that obtain regulatory approval is uncertain. Government authorities, private health insurers and other third-party payors decide which drugs they will cover and establish reimbursement levels for them, and obtaining coverage and reimbursement approval for a product from any such third-party payors is a time consuming and costly process. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. As a result, any denial of private or government payor coverage or inadequate reimbursement for our drug candidates, if any are commercialized, could harm our business and reduce our prospects for generating revenue.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. Existing legislation aimed at patient affordability in the U.S. may be repealed or replaced. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our drug candidates to other available therapies. If reimbursement of our drug candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country.

### We have no experience selling, marketing or distributing products and currently have no internal marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not be able to effectively market and sell our drug candidates, if approved, or generate product revenues.

We currently have no sales, marketing or distribution capabilities and there can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any drug candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Therefore, with respect to the commercialization of all or certain of our drug candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products.

If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our drug candidates that receive regulatory approval or any such

commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our products, we may in the future need to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our drug candidates, which could be expensive and time consuming and which would require significant attention of our executive officers to manage. Further, may not have sufficient resources to allocate to the sales and marketing of our products.

Any failure or delay in the development of sales, marketing and distribution capabilities, through collaboration with one or more third parties or through internal efforts, would adversely impact the commercialization of any of our products that we obtain approval to market. As a result, our future product revenue will suffer and we may incur significant additional losses.

# We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological advances. In addition, the competition in the anemia, asthma and cancer markets is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, fully integrated pharmaceutical or biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, and other public and private research organizations.

There are several third party drug candidates that could be competitive with drug candidates in our pipeline.

Drug candidates interfering with hepcidin function and thus competing with PRS-080 include those that are being developed by Noxxon (NOX-H94), Lilly (LY-2787106, LY-2928057), Ferrumax (FMX-8), ISIS/Xenon (XEN701), and Alnylam (ALN-HPN). Drug candidates interfering with the function of type 2 helper T cells, or Th2, the biological pathway for PRS-060, and thus competing with PRS-060, include those that are being developed by Sanofi/Regeneron (dupilimab), Roche/Genentech (lebrikizumab), Astra-Zeneca (tralokizumab, benralizumab), GSK (mepolizumab) and Teva (reslizumab). Drugs targeting immunomodulatory targets and thus competing with our 300-Series programs include those that are currently marketed by Bristol- Myers Squibb (Yervoy/ipilimumab, Opdivo/ nivolumab) and Merck (Keytruda/pembrolizumab) and drug candidates are developed by Bristol -Myers Squibb (Urelumab / anti-CD137; anti-LAG3; Anti-CD40; Lirilumab/ anti-KIR), Roche / Genentech (MPDL3280A/anti- PDL-1; RG7888 /anti-Ox40), Merck Serono (Avelumab / anti-PDL-1) and AstraZeneca (MEDI4736 / anti-PDL-1; MEDI0680 / anti-PD-1; MEDI6469/ Ox-40; tremelimumab/anti-CTLA-4). For additional information about our third party drug candidates which could be competitive with the drug candidates in our pipeline, see "Business—Competition."

These existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenue and our business will suffer.

Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing organizations, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and clinical trials;
- · obtaining FDA and other regulatory approvals of drugs;

- prosecuting and enforcing intellectual property rights;
- · formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of or in-license novel compounds that could make our drug candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval, or discovering, developing and commercializing medicines before we do, which would have a material adverse effect on our business and ability to achieve profitability from future sales of our approved drug candidates, if any. For additional information about our competitors, please see "Business—Competition."

# We could be subject to product liability lawsuits based on the use of our drug candidates in clinical testing or, if obtained, following marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our drug candidates.

We could be subject to product liability lawsuits if any drug candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop on our own or with collaborators. We do not currently carry general product liability insurance. We have put in place applicable product liability insurance, covering us as sponsor and the investigators involved in our Phase Ib clinical trial of PRS-080 in healthy volunteers, in an amount of up to the lesser of €0.5 million (\$0.5 million) per enrolled subject or €10 million (\$10.5 million) for the Phase Ib clinical trial in its entirety. In the future, we will seek to obtain similar insurance coverage with respect to any future clinical trials of our other drug candidates, such as PRS-060 and our 300-Series programs, but we may not be able to obtain the levels of coverage desired on acceptable terms, or at all. If we do secure product liability insurance, we may subsequently determine that additional amounts of coverage would be desirable at later stages of clinical development of our drug candidates or upon commencing commercialization of any drug candidate that obtains required approvals, but we may not be able to obtain such additional coverage amounts when needed on acceptable terms, or at all. Unless and until we obtain such insurance, we would be solely responsible for any product liability claims relating to our preclinical and clinical development activities. Further, even after any such insurance coverage is obtained, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by any insurance policies we may then have or that is in excess of the limits of our insurance coverage. We would be required to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by any product liability insurance we may obtain, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

# If we breach any of the agreements under which we license from third parties the intellectual property rights or commercialization rights to our drug candidates, particularly our license agreements with TUM and Enumeral, we could lose license rights that are important to our business and our operations could be materially harmed.

Under the TUM License Agreement, we in-license significant intellectual property related to our Anticalin® platforms from Technische Universität München, or TUM. Under the terms of the agreement, TUM assigns to us



certain materials and records resulting from the research. We retain rights to inventions made by our employees, and TUM assigns to us all inventions made under the agreement jointly by our employees and TUM personnel, provided that our employees have made a certain inventive contribution. With respect to all other inventions made in the course of the research, TUM grants to us worldwide exclusive license rights under patents and patent applications claiming such inventions. TUM retains rights to practice these inventions for research and teaching purposes. We bear the costs of filing, prosecution and maintenance of patents assigned or licensed to us under the agreement.

As consideration for the assignments and licenses we are obliged to pay to TUM milestone payments on development of our proprietary products claimed by patents assigned or licensed to us by TUM. We also are obliged to pay low single-digit royalties, including annual minimum royalties, on sales of such products. Should we grant licenses or sublicenses to those patents to third parties, we are obliged to pay to TUM certain undisclosed variable fees as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fees are creditable against annual license payments to TUM. Our payment obligations are reduced by our proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement.

Under the Definitive License and Transfer Agreement with Enumeral Biomedical Holdings, Inc. or Enumeral., we in-licensed intellectual property related to an Enumeral-generated antibody against PD-1 and an option to in-license up to two additional antibodies against undisclosed targets. Under the terms of the agreement, we acquired a non-exclusive worldwide license under the applicable Enumeral patents and know-how to research, develop and commercialize fusion proteins incorporating Enumeral's PD-1 antibody and one or more Anticalin proteins.

As consideration, we are obliged to pay to Enumeral development and sales milestones on development of products incorporating the Enumeral antibody. We are also obliged to pay low to lower-middle single-digit royalties as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that we are required to pay a license fee or royalty to any third party related to the licensed products, our royalty payment obligations to Enumeral are reduced by the amount of such third party fees or payments, up to 50% of the royalty payment for each calendar year due to Enumeral. Payment obligations terminate on a product-by-product and country-by-country basis on the later of ten years from the first commercial sale of a product incorporating the Enumeral antibody or the last to expire, lapse or be abandoned of a claim from the licensed Enumeral patents filed as of the effective date of the agreement that cover the manufacture, use, offer for sale, sale or import of a product incorporating the Enumeral antibody.

In addition to the TUM License Agreement and the Definitive License and Transfer Agreement with Enumeral, or the Enumeral License Agreement, we may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential drug candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of the TUM License Agreement or the Enumeral License Agreement, or any future license agreement we may enter on which our business or drug candidates are dependent, TUM or Enumeral or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain drug candidates, including, with respect to the TUM License Agreement and Enumeral License Agreement, our Anticalin drug therapies. Under the TUM License Agreement, we can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate our rights in patents assigned to us but would terminate our rights to Enumeral. Enumeral may terminate the Enumeral License Agreement, we can terminate the agreement upon 30 days' notice to Enumeral. Enumeral may terminate the Enumeral License agreement with TUM or Enumeral, or any future license agreement that we may enter granting us rights on which our business or drug candidates are dependent, would eliminate our ability to further develop the applicable drug candidates and would materially harm our business, prospects, financial condition and results of operations.

### Risks Related to Managing Any Growth We May Experience

# We will need to grow the size of our organization, and we may not successfully manage any growth we may achieve.

Our success will depend upon the expansion of our operations and our ability to successfully manage our growth. Our future growth, if any, may place a significant strain on our management and on our administrative, operational, and financial resources requiring us to implement and improve our operational, financial, and management systems.

In addition, our ability to manage our growth effectively will hinge upon our ability to expand, train, manage and motivate our employees. As of March 20, 2017, we have 49 full-time employees and 3 part-time employees. As our development and commercialization plans and strategies develop, these demands may also require the hiring of additional research, development, managerial, operational, sales, marketing, financial, accounting, legal, and other personnel.

Moreover, future growth could require the development of additional expertise by management and impose significant added responsibilities on members of management, including:

- effectively managing our clinical trials and submissions to regulatory authorities for marketing approvals;
- effectively managing our internal research and development efforts such as discovery research and preclinical development;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- effectively managing our internal and external business development efforts with current or future partners, such as entering into additional collaboration arrangements and increasing out-licensing revenues;
- establishing relationships with third parties essential to our business and ensuring compliance with our contractual obligations to such third parties;
- developing and managing new divisions of our internal business, including any sales and marketing segment we elect to establish;
- maintaining our compliance with public company reporting and other obligations, including establishing and maintaining effective internal control over financial reporting and disclosure controls and procedures; and
- improving our managerial, development, operational and finance systems.

We may not be able to accomplish any of those tasks, and our failure to do so could prevent us from effectively managing future growth, if any, and successfully growing our company.

Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial, and management systems could have a material adverse effect on our business, financial condition and results of operations.

# We may make future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.

We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue common stock or other forms of equity that would dilute our existing stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- challenges in achieving strategic objectives, cost savings and other anticipated benefits;
- increases to our expenses;
- the assumption of significant liabilities that exceed the limitations of any applicable indemnification provisions or the financial resources of any indemnifying party;
- inability to maintain relationships with key customers, vendors and other business partners of the acquired businesses;
- diversion of management's attention from their day-to-day responsibilities;
- · difficulty in maintaining controls, procedures and policies during the transition and integration;
- entrance into marketplaces where we have no or limited prior experience and where competitors have stronger marketplace positions;
- · potential loss of key employees, particularly those of the acquired entity; and
- that historical financial information may not be representative or indicative of our results as a combined company.

# If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively and our business would be harmed.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to, or misappropriation by, third parties of our proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding any competitive advantage we may derive from the proprietary information.

The strength of patents in the biotechnology and pharmaceutical fields can be uncertain and involve complex legal and scientific questions. No consistent policy regarding the breadth of claims allowed in patents has emerged to date in the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced, or that the scope of any patent rights could provide a sufficient degree of protection that could permit us to gain or keep our competitive advantage with respect to these products and technologies. For example, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings (e.g. at the United States Patent and Trademark Office, or the USPTO, or the European Patent Office, or the EPO) in connection with patent rights, which may be costly whether we win or lose.

As a result, the patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may issue as patents in the future, which may result in those patents being



narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the patents we hold or pursue is threatened, our ability to commercialize any drug candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the period of time during which we would have patent protection for any covered drug candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our drug candidates.

While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for our drug candidates, the applicable patents may not meet the specified conditions for eligibility for any such term extension and, even if eligible, we may not be able to obtain any such term extension. Further, because filing, prosecuting, defending and enforcing patents in multiple jurisdictions can be expensive, we may elect to pursue patent protection relating to our drug candidates in only certain jurisdictions. As a result, competitors would be permitted to use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, any of which could compete with our drug candidates.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery platform and drug development processes that involve proprietary know-how, information or technology that is not covered by patents or not amenable to patent protection. Although we require all of our employees and certain consultants and advisors to assign inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secrets and other intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could adversely affect our market position and business and operational results.

#### Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts.

Our research, development and commercialization activities, as well as any drug candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims that cover the use or manufacture of our drug candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our drug candidates infringes upon one or more claims of these patents. If our activities or drug candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block our ability to commercialize such drug candidates or practice our methods unless we obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or unenforceable.

Defense of any intellectual property infringement claims against us, regardless of their merit, would involve substantial litigation expense and would be a significant diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties, limit our business to avoid the infringing activities, pay royalties and/or redesign our infringing drug candidates or alter related formulations, processes, methods or other technologies, any or all of which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on reasonable terms, or at all. Some of our competitors may be able to sustain the costs of complex patent litigation or proceeding more effectively than us due to their substantially greater resources. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our drug candidates and our business could materially suffer.

# We may desire to, or be forced to, seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms or at all.

Third parties may also hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates, in which case we would need to obtain a license from that third party or develop a different formulation of the product that does not infringe upon the applicable intellectual property, which may not be possible. Additionally, we may identify drug candidates that we believe are promising and whose development and other intellectual property rights are held by third parties. In such a case, we may desire to seek a license to pursue the development of those drug candidates. Any license that we may desire to obtain or that we may be forced to pursue may not be available when needed on commercially reasonable terms or at all. Any inability to secure a license that we need or desire could have a material adverse effect on our business, financial condition and prospects.

# The patent protection covering some of our drug candidates may be dependent on third parties, who may not effectively maintain that protection.

While we expect the right to fully prosecute any patents covering drug candidates, we may in-license from third-party owners; it is possible that the platform technology patents that cover our drug candidates remain controlled by our licensors. Similarly, some of our future licensing partners may retain the right, or may seek the rights, to prosecute patents covering the drug candidates we license to them and we may grant such rights to those partners for business reasons. If such third parties fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected drug candidates may suffer.

# Certain technologies and patents have been developed with partners and we may face restrictions on this jointly developed intellectual property.

We have entered into agreements with a number of commercial partners, including university partners, which cover intellectual property. We have, in some cases individually and in other cases along with our partners, filed for patent protection for a number of technologies developed under these agreements and may in the future file for further intellectual property protection and/or seek to commercialize such technologies. Under some of these agreements, certain intellectual property developed by us and the relevant partner may be subject to joint ownership by us and the partner and our commercial use of such intellectual property may be restricted, or may require written consent from, or a separate agreement with, the partner. In other cases, we may not have any rights to use intellectual property solely developed and owned by the partner. If we cannot obtain commercial use rights for such jointly owned intellectual property or partner-owned intellectual property, our future product development and commercialization plans may be adversely affected.

#### We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, timeconsuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can be expensive and time-consuming and distract management.

If we pursue any litigation, a court may decide that a patent of ours or any of our licensors' is not valid or is unenforceable, or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of, or the amount of damages that could be awarded resulting from, any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in those jurisdictions.

Interference proceedings provoked by third parties or brought by the USPTO or at its foreign counterparts (such as the EPO) to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all.

Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

# If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development, our business and competitive position would be harmed.

We are seeking patent protection of our technology and for our drug candidates. Patent prosecution is a challenging process and is not assured of success. If we are unable to secure patent protection for our technology and drug candidates, our business may be adversely impacted.

In addition, issued patents and pending applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, for example by rendering issued patents unenforceable or by prematurely terminating pending applications.

#### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our Anticalin-brand technology and some of our drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We currently, and expect in the future to continue to, seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors, investigators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

# If we fail to protect our trademark rights, competitors may be able to take advantage of our goodwill, which would weaken our competitive position, reduce our revenues and increase our costs.

We believe that the protection of our trademark rights is an important factor in product recognition, maintaining goodwill, and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register, maintain and enforce our trademark rights. If we do not adequately protect our rights in our trademarks from infringement, any goodwill that we have developed in those trademarks could be lost or impaired.



Third parties may claim that the sale or promotion of our products, when and if we have any, may infringe on the trademark rights of others. Trademark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business. If the trademarks we use are found to infringe upon the trademark of another company, we could be liable for damages and be forced to stop using those trademarks, and as result, we could lose all the goodwill that has been developed in those trademarks.

#### Certain of our employees and their inventions are subject to German law.

Many of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants 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 can occur between us and such employees or ex-employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees retained rights to patents they invented or co-invented prior to 2009. Although most of these employees have subsequently assigned their interest in these patents to us, there is a risk that the compensation we provide to them may be deemed insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

#### The future growth of our business may expose our intellectual property to a high risk of counterfeiting or unauthorized use.

As part of our business strategy, we intend to license our Anticalin technology and sell our potential products, if any, in many different countries. As a result, we may do business with third parties in countries where intellectual property rights have been or are routinely disregarded, and the future growth of our business may expose our intellectual property to a high risk of counterfeiting or unauthorized use. Although we attempt to obtain broad international intellectual property rights for our Anticalin technology and proteins, we cannot guarantee that such rights, to the extent we can obtain them, will be enforceable in a timely fashion or at all in any particular country or jurisdiction, or that if enforced, will offer us adequate commercial protection or adequate redress for any harm suffered. Counterfeiting or unauthorized use of our technologies or products may also expose our business to harm for which no adequate monetary redress exists, and to the extent we are unable to stop such use, may cause us to lose rights with respect to intellectual property that is crucial to our business. Any such misuse of our intellectual property may have a substantial negative impact on our business and revenues, and may cause our business to fail.

#### **Risks Related to our Employees**

#### If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified personnel. We are highly dependent on our management, scientific and medical personnel, especially Stephen S. Yoder, our Chief Executive Officer and President, whose services are critical to the successful implementation of our drug candidate development, our business development and partnerships, and our regulatory and commercialization strategies. Further, as our approach is build upon the drug discovery and development experience of our drug development team, which we believe is a significant contributor to our competitive advantage, we are dependent on the maintenance and growth of that team with qualified members containing high levels of expertise in specific scientific fields. We may in the future hire additional employees for research and development or general and administrative activities.

We are not aware of any present intention of any of our executive officers or other members of our senior management team to leave our company, but our industry tends to experience a high rate of turnover of management personnel and our employees are generally able to terminate their relationships with us on short notice. Pursuant to German employment law, our employment arrangements with employees of Pieris GmbH are governed by employment contracts, which provide certain defined terms for either party to terminate the employment relationship.

The loss of the services of any of our executive officers, in particular Mr. Yoder, or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior and mid-level managers as well as junior and mid-level scientific and medical personnel.

Moreover, there is intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other related businesses. Many of the other companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles, longer histories in the industry and greater ability to provide valuable cash or stock incentives to potential recruits than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we are able to offer as an early stage company. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize drug candidates will be limited.

#### We may be subject to labor claims brought by our employees against us.

In the United States, an employment relationship with no specified duration is presumed to be employment "at-will" and the employer or employee may terminate the employment relationship at any time, with or without cause, except for public policy reasons including discrimination, participating in union activity, or refusing to carry out an activity that violates the law.

In contrast, in Germany, there is no analogous doctrine of "employment at will". By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. Our relations between German employees and employees are extensively regulated under German labor and employment laws and regulations. German employees have special protection against dismissals provided the employee has been employed by a company for more than six months and such company employs more than ten employees.

German employment termination law is regulated by various codes, in particular the *Kündigungsschutzgesetz* (German Termination Protection Act) and is intended to give the employee maximum protection against unfair dismissal, including among other things:

- the employer must observe the applicable notice period, which is ordinarily determined by law (between four weeks and seven months, depending upon the length of employment), if a longer period is not otherwise agreed by the parties, and has to deliver a written notice of termination to the employee;
- for companies with more than ten employees, the German Termination Protection Act generally restricts termination of
  employment if the employee has been employed for more than six months, wherein the employee may be terminated only for a
  particular reason, including certain behavioral or personal reasons relating to the employee or certain developments relating to the
  business of the employer, such as a business restructuring which reduces the number of employee positions;
- special termination protection against unlawful dismissal applies to several other groups of employees, such as an employee that
  is an officially acknowledged handicapped person, an employee who was appointed as a company's data protection officer or as a
  member of the works council of a company, if any, an employee on three years' maternity leave or a pregnant employee; in these
  cases, approval of various German authorities is required prior to termination but usually very difficult to obtain; and
- if a company engages in a mass layoff, which is deemed to occur when the employer intends to dismiss a large percentage of its employees during a one-month period, prior written notification to the German employment office is required.



In this regard, if we downsize Pieris for any reason and fail to adhere to the complex requirements articulated by the employee protection law, we could face legal actions brought by affected employees or former employees, and, as a result, we may incur operational or financial losses and the attention of our executive officers may be distracted from managing our business.

# We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employers. Litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees and contractors, who may be involved in the development of intellectual property, to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact contributes to the development of intellectual property that we regard as our own. Further, the terms of such assignment agreements may be breached and we may not be able to successfully enforce their terms, which may force us to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of intellectual property rights we may regard and treat as our own.

# Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause our business to suffer.

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, provide accurate information to the FDA or EMA, comply with manufacturing standards we have established, comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, report financial information or data accurately or 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. It is not always possible to identify and deter employee misconduct, and the precautions and procedures we currently take or may establish in the future as our operations and employee base expand to detect and prevent this type of 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 by our employees to comply with such 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 and results of operations, including the imposition of significant fines or other sanctions.

#### **Risks Related to the Ownership of our Common Stock**

#### Our share price is expected to be volatile and may be influenced by numerous factors, some of which are beyond our control.

Market prices for shares of biotechnology companies such as ours are often volatile, and the quoted price of our common stock is therefore likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the drug candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those drug candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our drug candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our drug candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our drug candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our drug candidates;
- our dependence on third parties, including CROs and CMOs as well as our current and potential partners that produce companion diagnostic products;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- · actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- · conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- · ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- · effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition, other biotechnology companies or our competitors' programs could have positive or negative results that impact their stock prices and their results or stock fluctuations could have a positive or negative impact on our stock price regardless of whether such impact is direct or not. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

# If securities or industry analysts do not publish, or cease publishing, research or publish inaccurate or unfavorable research about our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and any trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business, markets or competitors. Securities and industry analysts do not currently, and may never, publish research on us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

# We have identified a material weakness in our internal control over financial reporting. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors. However, as discussed in detail below, as an emerging growth company, we are not required to obtain an auditor attestation.

We have identified a material weakness in our internal control over financial reporting related to relating to the technical accounting for complex transactions and, as a result of such weakness, our management concluded that our disclosure controls and procedures and internal control over financial reporting were not effective as of June 30, 2016. During the period we noted an error in the accounting for our equity transaction. The error was corrected in the financial statements prior to their issuance. Notwithstanding the material weakness, we have concluded that the financial statements and other financial information included in this Annual Report on Form 10-K, fairly represent in all material respects our financial condition, results of operations, and cash flows as of, and for, the periods presented. For further information regarding this matter and the related material weakness, please refer to Item 9A. Controls and Procedures.

Although we are taking steps to remediate the material weakness in our internal control over financial reporting, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all. If we are unable to successfully remediate our material weakness, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, issuers that qualify as "emerging growth companies" under the JOBS Act will not be required to provide an auditor's attestation report on internal controls for so long as the issuer qualifies as an emerging growth company. We currently qualify as an emerging growth company under the JOBS Act, and we may choose not to provide an auditor's attestation report on internal controls. However, if we cannot favorably assess the effectiveness of our internal control over financial reporting, or if we require an attestation report from our independent registered public accounting firm in the future and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be

evaluated frequently. Our failure to remediate our material weakness in internal controls and thereafter to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on the tradability of our common stock, which in turn would negatively impact our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

# Shares of our common stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former "shell company."

Prior to the closing of the Acquisition, we were deemed a "shell company" under applicable SEC rules and regulations because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Form 8-K reports. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future. The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline.

#### If we issue additional shares of our capital stock in the future, our existing stockholders will be diluted.

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 300,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the terms, limitations, voting rights, relative rights and preferences and variations of each series that our Board of Directors may determine from time to time. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Additionally, issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock, and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

# Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2016, a total of 43,058,827 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.



# The resale of shares covered by our effective resale registration statement could adversely affect the market price of our common stock in the public market, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional equity capital. Pursuant to registration statements filed with the SEC, (i) we have registered for resale 27,321,870 shares of our common stock, which represents all of the shares of our common stock issued and sold in our private placement consummated in December 2014, shares of our common stock issued to former stockholders of Pieris GmbH in connection with the closing of the Acquisition on December 17, 2014, and shares of common stock issuable upon exercise of common stock purchase warrants issued in connection with the closings of the private placement in December 2014 and (ii) registered for resale (x) 3,225,804 shares of our common stock, (y) 4,963,000 shares of common stock issuable upon the conversion of 4,963 shares of our Series A Convertible Preferred Stock, par value \$0.001 per share, and (z) 4,913,280 shares of common stock issuable upon exercise of common stock purchase warrants, which represents all of the securities issued and sold in our private placement consummated in June 2016 . Such shares represented approximately 76% of our outstanding shares of common stock as of March 20, 2017. The resale registration statement permits the resale of these shares at any time without restriction. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statement, we may continue to offer shares covered by the resale registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the resale registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

# Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or otherwise, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Even after giving effect to the funds raised in the past, we expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

Pursuant to our 2016 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 3,750,000 shares of our common stock, plus shares granted under the 2014 Plan that expired or were cancelled on or after June 28, 2016, and as of December 31, 2016, we have granted options to purchase 4,440,376 shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

#### Anti-takeover provisions in our organizational documents could delay or prevent a change of control.

Certain provisions of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws may have an anti-takeover effect and may delay, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider to be in its interests, including attempts that might result in a premium over the market price for the shares held by our stockholders.

These provisions provide, among other things:

- a classified Board of Directors with staggered three-year terms;
- the ability of our Board of Directors to issue one or more series of preferred stock with voting or other rights or preferences that could have the effect of impeding the success of an attempt to acquire us or otherwise effect a change of control;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at stockholder meetings;
- certain limitations on convening special stockholder meetings and the prohibition of stockholder action by written consent; and
- directors may only be removed for cause and only by the affirmative vote of the holders of at least eighty percent (80%) of the voting power of all of the then-outstanding shares of our capital stock entitled to vote at an election of directors, voting together as a single class.

These anti-takeover provisions, including those noted above, could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. See "Description of Capital Stock".

#### Our Amended and Restated Articles of Incorporation designates the Eighth Judicial District Court of Clark County, Nevada, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and therefore limit our stockholders' ability to choose a forum for disputes with us or our directors, officers, employees or agents.

Our Amended and Restated Articles of Incorporation provide that, to the fullest extent permitted by law, and unless we consent to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for any (i) derivative action or proceeding brought in the name or right of the corporation or on its behalf, (ii) action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to the corporation or any of our stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Chapters 78 or 92A of the Nevada Revised Statutes or any provision of our articles of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our Amended and Restated Articles of Incorporation further provide that any person purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed, to the fullest extent permitted by law, to have notice of and consented to the foregoing provision.

We believe the choice-of-forum provision in our Amended and Restated Articles of Incorporation will help provide for the orderly, efficient and cost-effective resolution of Nevada-law issues affecting us by designating courts located in the State of Nevada (our state of incorporation) as the exclusive forum for cases involving such issues. However, this provision may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or our directors, officers, employees or agents, which may discourage such actions against us and our directors, officers, employees and agents. While there is no Nevada case law addressing the enforceability of this type of provision, Nevada courts have on prior occasion found persuasive authority in Delaware case law in the absence of Nevada statutory or case law specifically addressing an issue of corporate law. The Court of Chancery of the State of Delaware ruled in June 2013 that choice-of-forum provisions of a type similar to those included in our Amended and Restated Articles of Incorporation are not facially invalid under corporate law and constitute valid and enforceable contractual forum selection clauses. However, if a court were to find the choice-of-forum provision in our Amended and Restated Articles of Incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.



# The elimination of personal liability of our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Amended and Restated Articles of Incorporation eliminate to the furthest extent permitted under Nevada law the personal liability of our directors and officers to us, our stockholders and creditors for damages as a result of any act or failure to act in his or her capacity as a director or officer. Further, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and individual indemnification agreements that we have entered with each of our directors and officers provide that we are obligated to indemnify, subject to certain exceptions, each of our directors or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for such damages, even if such actions might otherwise benefit our stockholders.

#### We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. We currently intend to retain all future earnings to fund the development and growth of our business. Any future payment of cash dividends in the future will be at the discretion of our Board of Directors and will depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that the Board of Directors deems relevant. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

# We will incur increased costs associated with, and our management will need to devote substantial time and effort to, compliance with public company reporting and other requirements.

As a public company listed on the NASDAQ Capital Market, and particularly if and after we cease to be an "emerging growth company" or a "smaller reporting company," we will incur significant legal, accounting and other expenses that we did not incur as a private company and that we did not incur prior to the listing of our common stock on the NASDAQ Capital Market, including costs associated with public company reporting requirements. In addition, the rules and regulations of the SEC and the NASDAQ Capital Market impose numerous requirements on public companies, including requirements relating to our corporate governance practices and requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, with which we will now need to comply. Further, since we are subject to the Exchange Act, we are required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We are unable currently to estimate these costs with any degree of certainty.

# We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company under the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public



Company Accounting Oversight Board. If we do, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to take advantage of this extended transition period. Since we will not be required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies, our financial statements may not be comparable to the financial statements of companies that comply with the effective dates of those accounting standards.

We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter, (2) the end of the fiscal year in which we have total annual gross revenues of \$1 billion or more during such fiscal year, (3) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (4) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Decreased disclosures in our SEC filings due to our status as an "emerging growth company" may make it harder for investors to analyze our results of operations and financial prospects.

# We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a "smaller reporting company", meaning that we are not an investment company, an asset-backed issuer, or a majorityowned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$75 million and annual revenues of less than \$50 million during the most recently completed fiscal year. In the event that we are still considered a "smaller reporting company," at such time we cease being an "emerging growth company", we will be required to provide additional disclosure in our SEC filings. However, similar to "emerging growth companies", "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in a registration statement under the Exchange Act on Form 10. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our results of operations and financial prospects.

#### Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

#### Item 2. **PROPERTIES**

We lease 1,414 square meters of office and laboratory space in Freising, Germany. This lease may be terminated by either party subject to an 8-month notice period, provided, that such period must finish at a quarter end period. We also lease 235 square meters of office space in Freising, Germany. The term of the lease expires in June 2018. We lease 3,950 square feet of office space in Boston, MA under a sublease that houses our executive offices and certain administrative functions. This sublease shall expire on February 27, 2022 or such earlier date pursuant to the termination provisions of the Sublease Agreement. We believe that our facilities are sufficient to meet our needs and will look for suitable additional space as and when needed.

# Item 3. LEGAL PROCEEDINGS

As of the date of this Annual Report on Form 10-K, we are not currently involved in any material legal proceedings. However, from time to time, we could be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

## Item 4. MINE SAFETY DISCLOSURES

Not applicable.

# PART II

# Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### **Market Information**

Our common stock is quoted on the Nasdaq Capital Market under the symbol "PIRS." On June 30, 2015 our common stock began trading on the Nasdaq Capital Market. Our common stock was first publicly traded on the OTC Markets, OTCPink tier of the OTC Markets Group, Inc commencing on January 28, 2015. The following table sets forth, for the periods indicated, the high and low closing bid quotations for our common stock, as reported by NASDAQ, since the common stock commenced public trading:

Common Stool

	Commo	Common Stock	
	High	Low	
Year Ended December 31, 2016:			
First Quarter	\$2.29	\$1.49	
Second Quarter	\$2.41	\$1.60	
Third Quarter	\$1.83	\$1.55	
Fourth Quarter	\$1.96	\$1.36	
Year Ended December 31, 2015:			
First Quarter	\$3.25	\$2.75	
Second Quarter	\$4.40	\$2.00	
Third Quarter	\$3.70	\$1.74	
Fourth Quarter	\$3.08	\$1.54	

#### Stockholders

As of March 20, 2017, there were 143 and 5 stockholders of record of our common stock and preferred stock, respectively.

#### Dividends

We have never declared nor paid any cash dividends to stockholders. We do not intend to pay cash dividends on our common stock for the foreseeable future, and currently intend to retain any future earnings to fund our operations and the development and growth of our business. The declaration of any future cash dividend, if any, would be at the discretion of our Board of Directors (subject to limitations imposed under applicable Nevada law) and would depend upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions.

#### **Unregistered Sales of Securities**

On November 26, 2016, we issued an option grant to Claude Knopf, our Chief Business Officer, as a new hire inducement grant pursuant to NASDAQ Listing Rule 5635(c)(4) and Section 4(a)(2) of the Securities Act. Claude Knopf's option grant is for the purchase of an aggregate of 500,000 shares of Common Stock at a price per share of \$1.45 subject to his continued employment with us.

#### **Issuer Purchases of Equity Securities**

None.

# Item 6. SELECTED FINANCIAL DATA

Not applicable.

# Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties as described under the heading "Forward-Looking Statements" elsewhere in this Annual Report on Form 10-K. You should review the disclosure under the heading "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### Overview

We are a clinical-stage biotechnology company that discovers and develops Anticalin based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immune-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of low molecular-weight therapeutic proteins derived from lipocalins, which are naturally occurring low-molecular weight human proteins typically found in blood plasma and other bodily fluids.Each of our development programs focus on the following:

- *300-Series oncology drug candidates* are multispecific Anticalin-based proteins designed to engage immunomodulatory targets and consist of a variety of multifunctional biotherapeutics that genetically link an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein;
- PRS-343 our lead immune-oncology program is a 4-1BB/HER2 bispecific, comprised of a HER2-targeting antibody genetically linked to a 4-1BB-targeting Anticalin, in which tumor-targeted drug clustering mediated by HER2 expressed on certain solid tumors is intended to drive tumor localized T cell activation for patient unresponsive to current standard of care.
- *PRS-332* is a bispecific anticalin-antibody fusion protein comprising an anti-PD-1 antibody genetically fused to an Anticalin targeting an undisclosed checkpoint target. In order to improve on existing PD-1 therapies, we are developing PRS-332 with the intent to simultaneously block PD-1 and another immune checkpoint co-expressed on exhausted T cells.
- *PRS-080* is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. It has been designed to target hepcidin for the treatment of functional iron deficiency in anemic patients with chronic kidney disease particularly in end-stage renal disease patients requiring dialysis.
- *PRS-060* is a drug candidate that binds to the IL-4RA receptor, thereby inhibiting IL-4 and IL-13, two cytokines, small proteins mediating signaling between cells within the human body, known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases.

Our programs are in varying stages:

- 300-Series—We are conducting activities relating to lead candidate identification, lead candidate optimization, preclinical evaluation and IND filing preparation on several of our 300-Series lead candidates.
  - Our lead candidate, PRS-343, has been advanced through IND-enabling studies in 2016. Preclinical safety and efficacy studies were performed. A Master Cell bank was generated and GMP material to support initial clinical trials has been produced. We intend to file an IND and initiate a Phase I clinical trial in HER2 positive solid tumor for PRS-343 in the first half of 2017; and
  - PRS-332—We expect to nominate a development candidate and initiate IND-enabling activities in the second half of 2017.



- PRS-080—We completed a Phase Ia single-ascending dose clinical trial with PRS-080 in healthy volunteers in 2015. Based on the data we obtained in the Phase Ia clinical trial, we initiated a Phase Ib clinical study in CKD 5 patients requiring hemodialysis which we expect to complete by the first quarter of 2017. Data un-blinding and subsequent disclosure is currently planned for the second quarter of 2017. The company plans to initiate in the second quarter of 2017 a multi-dose clinical study in CKD patients requiring hemodialysis, which will assess the ability of PRS-080 to elevate hemoglobin over a period of approximately four weeks.
- PRS-060—We have formulated PRS-060 for pulmonary delivery by inhalation and we have developed a bioprocess that has generated GMP material for use in preclinical safety and tolerability studies and First in Human clinical studies. We intend to pursue a first-in-human clinical trial for PRS-060 in the second half of 2017.

Our core Anticalin<sup>®</sup> technology and platform was developed in Germany, and we have partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India. These include existing agreements with Daiichi Sankyo Company Limited ("Daiichi"), and Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA, "Sanofi") and F.Hoffman—La Roche Ltd. and Hoffmann—La Roche Inc., ("Roche"), pursuant to which our Anticalin platform has consistently achieved its development milestones. Furthermore, we established collaborations with Les Laboratoires Servier and Institut de Recherches Internationales Servier (together "Servier") in January 2017 and with Aska Pharmaceuticals Co., Ltd. ("Aska") in February 2017. We have discovery and preclinical collaboration and service agreements with both academic institutions and private firms in Australia. Since inception, we have devoted nearly all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. For the years ended December 31, 2016 and 2015, we reported net loss of \$22.8 million and \$14.1 million, respectively. As of December 31, 2016, we had an accumulated deficit of \$102.7 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the fiscal years ended December 31, 2016 and 2015 were primarily from license and collaboration agreements with our partners, and, to a lesser extent, from grants from government agencies.

A significant portion of our operations are conducted in countries other than the United States. Since we conduct our business in U.S. dollars, our main exposure, if any, results from changes in the exchange rates between the euro and the U.S. dollar. All assets and liabilities denominated in euros are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the average rate during the period. Equity transactions are translated using historical exchange rates. Adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive loss. We may incur negative foreign currency translation changes as a result of changes in currency exchange rates.

#### **Key Financial Terms and Metrics**

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial statements.

#### Revenues

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the last two years have been primarily from the license

and collaboration agreements with Sanofi, Daiichi, Roche and, to a much lesser extent, grants from government agencies.

The revenues from Sanofi, Daiichi and Roche have been comprised primarily of upfront payments, research and development services, and milestone payments. We recognized revenues from upfront payments under these agreements based on multiple-element arrangement guidance as we have determined that the licenses to which the payments related did not have standalone value. Research service revenue is recognized when the costs are incurred and the services have been performed. Revenue from milestone payments is recognized when all of the following conditions are met: (1) the milestone payments are non-refundable, (2) the probability of the achievement of the milestone is near certain, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment.

We expect our revenues for the next several years to consist of upfront payments, research funding and milestone payments from strategic collaborations we currently have or may establish in the future.

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

The process of researching and developing drugs for human use is lengthy, unpredictable, and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable, with any certainty, to estimate either the costs or the timelines in which those costs will be incurred. Our current development plans focus on four lead drug candidates: PRS-080, PRS-060, PRS-343, and PRS-332. These programs consume a large proportion of our current, as well as projected, resources.

Our research and development costs include costs that are directly attributable to the creation of certain of our Anticalin <sup>®</sup> drug candidates and are comprised of:

- · internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and
- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing and related testing, and clinical trial activities.

In 2017 we expect our research and development expenses to increase significantly as a result of continuing to further our drug candidates and programs.

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

General and administrative expenses consist primarily of payroll, employee benefits, equity compensation, and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with professional fees for accounting, auditing, insurance costs, consulting and legal services. In 2017, we expect our general and administrative expenses to increase further as we are planning to hire additional G&A staff.

### **Results of Operations**

### Comparison of Years Ended December 31, 2016 and December 31, 2015

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2016 and 2015 (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015	
Revenues	\$ 5,831	\$	2,932
Research and development expenses	(19,699)		(8,245)
General and administrative expenses	(8,891)		(8,368)
Other income (expense), net	122		(174)
Income tax provision	(162)		(204)
Net loss	\$ (22,799)	\$	(14,059)

### Revenues

The following table provides a comparison of revenues for the years ended December 31, 2016 and 2015 (in thousands):

	Years ended December 31,			
	2016	2015	\$- Change	%- Change
Upfront payments	\$2,736	\$ —	\$2,736	100%
Research and development services	1,440	6	1,434	23900%
Milestone payments	1,655	2,539	(884)	(35%)
Grants	—	369	(369)	(100%)
Other	—	18	(18)	(100%)
Total Revenue	\$5,831	\$2,932	\$2,899	99%

The \$2.7 million increase in revenues from upfront payments in the twelve months ended December 31, 2016 compared to the twelve months ended December 31, 2015 relates to the recognition of an upfront payment under our collaboration with Roche, which commenced in January 2016. The revenue for the upfront payment is recorded based on the proportionate performance method using full-time equivalents as a measure to recognize the upfront payment over the research term. No upfront payments were recognized for the twelve months ended December 31, 2015.

- The \$1.4 million increase in revenues from research and development services in the twelve months ended December 31, 2016 compared to the twelve months ended December 31, 2015 mainly relates to research and development services being provided to Roche, pursuant to the Roche Agreement.
- The \$0.9 million decrease in milestone revenue resulted from the achievement of one milestone received during the twelve months ended December 31, 2016 under our collaboration with Daiichi compared to two milestones achieved under our collaboration with Daiichi, and one milestone under our collaboration with Sanofi received during the twelve months ended December 31, 2015.
- The decrease in revenues from grants during the twelve months ended December 31, 2016 compared to the twelve months ended December 31, 2015 resulted from the end of the Seventh Research Framework Program, or FP7, under which the Company recognized \$0.4 million in the twelve months ended December 31, 2015. No grant revenues were recognized for the twelve months ended December 31, 2016 as the Company received the last tranche under the FP7 program in November 2015; no other programs under which the Company could receive government grants are currently in place.

#### Research and Development Expenses

The following table provides a comparison of the research and development expenses for our drug candidates and projects for the years ended December 31, 2016 and 2015 (in thousands):

		Years ended December 31,		
	2016	2015	\$- Change	%- Change
PRS-060	\$ 1,729	\$ 532	\$ 1,197	225%
PRS-080	1,355	1,631	(276)	(17%)
PRS-300 series	8,508	2,917	5,591	192%
Other R&D activities	8,107	3,165	4,942	156%
Total	\$19,699	\$8,245	\$11,454	139%

Total research and development expenses were \$19.7 million for the fiscal year ended December 31, 2016 as compared to \$8.2 million for the fiscal year ended December 31, 2015.

The \$11.5 million increase in total research and development expenses in the twelve months ended December 31, 2016 compared to the twelve months ended December 31, 2015 is primarily due to:

- · increase in chemistry, manufacturing, controls, or CMC, associated with PRS-060 as we carry out IND enabling studies;
- increased preclinical and CMC costs for PRS-343 as we carry out our IND enabling studies, and development costs for our other 300-Series programs;
- decreased expenses for PRS-080 due to a decrease in CMC costs. The Phase 1a clinical trial was completed in 2015; and
- increase in other R&D activities of \$4.9 million. This increase is primarily due to higher personnel-related expenses including stock-based compensation expense, increased costs for license fees related to TUM and Enumeral as well as higher legal and consulting costs. In addition, general lab supplies increased due to increased program activities in our non-core projects.

#### General and Administrative Expenses

General and administrative expenses were \$8.9 million for the fiscal year ended December 31, 2015 as compared to \$8.4 million for the fiscal year ended December 31, 2015. The increase of \$0.5 million resulted primarily from an increase of personnel related costs, including stock-based compensation expense, higher legal and recruiting costs, and costs associated with being a public company such as financial printing costs and transaction fees. These amounts are offset by lower consulting and insurance expenses.

#### Other Income (Expense), net

Other income increased to \$0.1 million in the fiscal year ended December 31, 2016 from an expense of \$0.2 million for the fiscal year ended December 31, 2015. This \$0.3 million increase in other income results from the \$0.2 million interest charge associated with the TUM arbitration settlement reached in the fourth quarter of 2015 and a \$0.1 million gain on foreign currency transactions.

#### Liquidity and Capital Resources

Through December 31, 2016, we have funded our operations with \$194.6 million of cash that has been obtained from the following main sources: \$117.9 million from sales of equity; \$6.5 million from loans; \$14.2 million from grants from government agencies; and \$56.0 million in total payments received under license and collaboration agreements, including \$13.2 million for research and development services costs from our collaboration partners.

We expect that reimbursements of our development costs by Daiichi Sankyo and Sanofi will decline going forward, and we do not expect such reimbursements to be a significant source of funding in the future.

As of December 31, 2016, we had a total of \$29.4 million in cash and cash equivalents.

We have experienced operating losses since its inception and had a total accumulated deficit of \$102.7 million as of December 31, 2016. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception including the year ended December 31, 2016. These losses have resulted in significant cash used in operations. Due to the upfront payment received from Roche during the twelve months ended December 31, 2016 offset with our net losses for the period, our net cash used in operating activities is \$14.4 million. During the twelve months ended December 31, 2015, our cash used in operations was \$12.7 million. We have several research and development programs underway in varying stages of development and we expect they will be continue to consume increasing amounts of cash for development, conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of our 300-Series, including PRS-343, PRS-080 and PRS-060 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years.

In July 2015, we closed a public offering of an aggregate of 9,090,909 shares of our common stock, par value \$0.001 per share at a purchase price of \$2.75 per share. On July 28, 2015, the underwriters exercised their option to purchase an additional 1,211,827 shares of common stock at the public offering price of \$2.75 per share. Gross proceeds from the public offering, including the over-allotment option, were \$28.3 million and net proceeds were approximately \$25.8 million.

In June 2016, we entered into a securities purchase agreement for a private placement with a select group of institutional investors. The private placement, referred to as the 2016 PIPE, consisted of the sale of 8,188,804 units at a price of \$2.015 per unit for gross proceeds to us of approximately \$16.5 million. After deducting for placement agent fees and offering expenses, the aggregate net proceeds from the 2016 PIPE was approximately \$15.3 million. Each unit, included in the 2016 private placement transaction, consisted of (i) one share of common stock or non-voting series A convertible preferred stock, par value \$0.001 per share, or the series A preferred shares, which are convertible into one share of common stock, (ii) one warrant to purchase 0.4 shares of common stock at an exercise price of \$2.00 per share, and (iii) one warrant to purchase 0.2 shares of common stock at an exercise price of \$3.00 per share. The 2016 PIPE transaction closed on June 8, 2016.

On August 3, 2016, our shelf registration statement in the amount of \$100 million was declared effective by the SEC. This registration allows us to offer for sale various unspecified classes of equity and debt securities. As circumstances warrant, we may issue debt and/or equity securities from time to time on an opportunistic basis, dependent upon market conditions and available pricing. We make no assurance that we can issue and sell such securities on acceptable terms or at all.

We believe that our effective shelf registration statement improves our ability to access capital.

In January 2017, the Company entered into a License and Collaboration Agreement and a Non-Exclusive Anticalin Platform Technology License Agreement with Les Laboratories Servier and Institut de Recherches Internationales Servier (collectively, "Servier"). Under the agreements, the Company will receive an upfront payment of \$31.3 million. The total development, regulatory and sales-based milestone payment to the Company could exceed \$1.8 million over the life of the collaboration. The Company believes the signing of the agreements with Servier improves the Company's liquidity profile.

We will need to obtain additional funding in order to continue our operations and pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements for at least the next twelve months. Our requirements for additional capital will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical studies, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates and any products that we may develop;
- the number and characteristics of drug candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- · the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We cannot be sure that future funding will be available to us on acceptable terms, or adequate enough at all. Due to often volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress for our 300-series programs, including PRS-343 and PRS-332, PRS-080 and PRS-060 could have a material adverse impact on our ability to raise additional capital.

We may seek to raise any necessary additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our drug candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through private or public equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

#### **Contractual Obligations**

#### Leases

We lease office and laboratory space in Freising, Germany, which has a defined termination date at the end of a notification period of eight months at the end of each quarter. Since June 2016, we lease additional office space in Freising; the lease will expire in June 2018. On August 27, 2015 we entered into an Agreement of Sublease (the "Sublease Agreement") with Berenberg Capital Markets LLC (the "Sublandlord"). Under the Sublease Agreement, the Sublandlord will sublease to us approximately 3,950 square feet in Boston, MA. The term of the lease shall expire on February 27, 2022. The Sublease Agreement provided free rent for the first two months in addition to scheduled rent increases that are not dependent on future events.

Our policy is to record rent expense on a straight-line basis over the lease term period. As of December 31, 2016 and December 31, 2015, we recognized rent expense in an amount of \$0.2 million and \$18,399, respectively.



Rent expense under our operating lease for our Freising, Germany based facility is \$0.3 million and \$0.4 million for the years ended December 31, 2016 and 2015, respectively.

Our contractual commitments of the non-cancellable portion under theses operating leases as of December 31, 2016 are as follows:

	Total
2017	\$ 391,042
2018	209,590
2019	195,909
2020	199,859
2021	203,809
Thereafter	34,563
Total minimum lease payments	\$1,234,772

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

#### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Management makes estimates and exercises judgment in revenue recognition, share-based payments and income taxes. Judgments must also be made about the disclosure of contingent liabilities, and these estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates and under different assumptions or conditions.

We have identified the following accounting policies that we believe require application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results could differ from these estimates and such differences could be material.

#### **Revenue Recognition**

#### Multiple-element arrangements

When evaluating multiple-element arrangements, we identify the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based whether the delivered element has stand-alone value to the collaborator or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. We used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because we do not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, we consider market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements,

similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating our best estimate of selling price, we evaluate whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

We typically receive upfront, nonrefundable payments when licensing our intellectual property in conjunction with a research and development agreement. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the stage of development of the license delivered, research capabilities of the partner and the availability of Anticalin technology research expertise in the general marketplace.

When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, we generally recognize revenue attributable to the license on a straight-line basis over our contractual or estimated performance period, which is typically the term of our research and development obligations. When management believes the license to its intellectual property has stand-alone value, we recognize revenue attributed to the license upon delivery. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue we record in future periods.

The accounting treatment for options granted to collaborators is dependent upon the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of an agreement, we are at risk as to whether the collaborative partner will choose to exercise the options to secure additional licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

In arrangements where options to obtain additional licenses are considered substantive, we determine whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and incremental discount, the option is considered a deliverable in the arrangement. However, if not priced at a discount, the elements included in the arrangement are considered to be only the non-contingent elements. When a collaborator exercises an option to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and we apply the multiple-element revenue recognition criteria to determine accounting treatment. All of our agreements with options have been determined to include substantive options.

Revenue resulting from our research and development services efforts in multiple-element arrangements in which our research and development service efforts are considered deliverable are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

#### Milestone payments

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation



includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

We aggregate milestones into four categories (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Sales milestones are typically achieved when an approved pharmaceutical product exceed net sales as defined in each agreement.

For revenues from research, development and sales milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the period of performance. To date, we have determined all milestones are substantive. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

#### Government grants

Government grants are recognized when there is reasonable assurance that all conditions will be complied with and the grant will be received. As the government grants generally represent subsidies for specified activities, they are recognized when earned as revenue from grants.

Funds received that are not related to research and development expenses that have already been incurred, such as the EUROCALIN grant, are recorded as deferred revenue until such time that the related expenses have been incurred by us or by one of the other members of the EUROCALIN consortium. At the time eligible expenses are incurred, the applicable portion of deferred revenue according to the respective funding rates is recorded as revenue from grants.

#### Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, we determine whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, we carry out an evaluation of disclosure requirements and consider possible accruals in the financial statements.

### Research and development expense

Research and development costs are charged to expense as incurred in performing research and development activities. The costs include employee compensation costs, non-clinical and clinical study costs, external consultant costs, regulatory costs, and facilities and overhead costs. Facilities and overhead costs primarily include the allocation of insurance, rent, utility and office-related expenses attributable to research and development personnel. The Company records payments made to outside vendors in advance of services performed or goods being delivered for use in research and development activities as prepaid and accrued expenses, which are expensed as services are performed or goods are delivered.

#### Income taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that its net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce its net deferred tax assets.

We recognize, measure, present and disclose in our financial statements any uncertain tax positions that we have taken, or expect to take on a tax return. We operate in multiple jurisdictions, both within and outside the United States, and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense.

#### **Recently Issued Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our consolidated financial statements, see "Note 2— Summary of Significant Accounting Policies" in our consolidated financial statements.

### **Emerging Growth Company and Smaller Reporting Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, establishes a class of company called an "emerging growth company," which generally is a company whose initial public offering was completed after December 8, 2011 and had total annual gross revenues of less than \$1 billion during its most recently completed fiscal year. Additionally, Section 12b-2 of the Exchange Act establishes a class of company called a "smaller reporting company," which generally is a company with a public float of less than \$75 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is \$0, had annual revenues of less than \$50 million during the most recently completed fiscal year for which audited financial statements are available. We currently qualify as both an emerging growth company and a smaller reporting company.

As an emerging growth company and a smaller reporting company, we are eligible to take advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including without limitation the following:

• An emerging growth company is exempt from 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 financial statements, commonly known as an "auditor discussion and analysis."

- An emerging growth company is not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders.
- Neither an emerging growth company nor a smaller reporting company is required to comply with the requirement of auditor attestation of management's assessment of internal control over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced financial statement disclosure in registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earliest of (i) December 31, 2019, the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) on the end of the fiscal year on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019. We will remain a smaller reporting company until we have a public float of \$75 million or more as of the last business day of our most recently completed second fiscal quarter, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

Emerging growth companies may elect to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

# Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

# Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements required by this Item are as set forth in Item 15 beginning on page F-1 of this Annual Report on Form 10-K.

# Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

### Item 9A. CONTROLS AND PROCEDURES

# **Evaluation of Disclosure Controls and Procedures**

Our management is responsible for establishing and maintaining "disclosure controls and procedures" as such term is defined in Rule 13a-15(e), under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as well as for establishing and maintaining "adequate internal control over financial reporting" as such term is defined in Rule 13a-15(f) under the Exchange Act. The Company's system of internal controls over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with generally accepted accounting principles.

Because of the inherent limitations surrounding internal controls over financial reporting, our disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management, under the supervision of and with the participation of the Chief Executive Officer and Acting Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting and disclosure controls and procedures as of December 31, 2016. In making this assessment, management used the updated criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment under the COSO Internal Control-Integrated Framework, management believes that, as of December 31, 2016, our internal control over financial reporting was not effective, as described below.

In connection with the preparation of our financial statements for the three and six months ended June 30, 2016, we concluded that we had a material weakness relating to the technical accounting for complex transactions. During the period we noted an error in the accounting for our equity transaction. The error was corrected in the financial statements prior to their issuance. We have developed and implemented a remediation plan for this material weakness. We will continue to execute our remediation plan, which includes, among other things, engagement of additional technical expertise, as needed, on complex accounting matters to support the accounting and finance team and the internal control environment.

Notwithstanding the material weakness, we have concluded that the financial statements and other financial information included in this Annual Report on Form 10-K, fairly represent in all material respects our financial condition, results of operations, and cash flows as of, and for, the periods presented.

# **Changes in Internal Control over Financial Reporting**

Except from the material weakness above, there have been no changes in internal control over financial reporting identified in connection with the evaluation of such internal control required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Item 9B. OTHER INFORMATION

Not applicable.

# PART III

### Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### MANAGEMENT

#### **Directors, Executive Officers and Other Non-Executive Officers**

The table below sets forth information about our directors and executive officers:

Name	Age	Position
Stephen S. Yoder	41	Chief Executive Officer, President and Director
Lance Thibault	50	Acting Chief Financial Officer
Louis A. Matis	66	Senior Vice President and Chief Development Officer
Claude Knopf	50	Senior Vice President and Chief Business Officer
Chau Khuong (1)(2)	41	Chairman of the Board of Directors
Michael Richman (1)(3)	56	Director
Jean-Pierre Bizzari (3)	62	Director
Steven Prelack (2)	59	Director
Julian Adams (3)	62	Director
Christopher Kiritsy (1)(2)	51	Director

(1) Member of the compensation committee

(2) Member of the audit committee

(3) Member of the nominating and corporate governance committee

#### **Business Experience**

The following is a brief account of the education and business experience of our current directors and executive officers:

*Stephen S. Yoder*. Stephen S. Yoder joined Pieris GmbH as Chief Executive Officer in January 2010 and was appointed to the Board of Directors of Pieris and became Chief Executive Officer and President in December 2014. Prior to joining Pieris GmbH, from July 2003 to December 2010 he led the intellectual property and legal departments at MorphoSys AG, a biotechnology company involved in the development and research of antibodies, as General Counsel. Prior to MorphoSys AG, from September 1999 to June 2003 he worked in several Washington, D.C. law firms, specializing in a life sciences intellectual property practice. Mr. Yoder holds degrees in molecular biology and Spanish from Grove City College and a Juris Doctorate, with honors, from The George Washington University Law School. As an attorney, he is licensed to practice before the United States Patent and Trademark Office, and in the jurisdictions of Maryland and Washington, D.C. We believe that Mr. Yoder adds value to our Board of Directors based on his intimate knowledge of our business plans and strategies of our business and his years of experience in the biotechnology and life sciences industry.

*Lance Thibault*. Lance Thibault was appointed Acting Chief Financial Officer on February 1, 2017 and provides his services pursuant to a consulting agreement with the financial advisory firm of Danforth Advisors, LLC where he has served as a consulting chief financial officer since January 2014, providing operational, financial and strategic services at a number of private pharmaceutical and biotechnology companies. Mr. Thibault's previous experience includes serving as interim chief financial officer of Proteostasis Therapeutics, Inc. (NASDAQ: PTI), as interim finance director for Paratek Pharmaceuticals, Inc. (NASDAQ: PRTK), and has provided specialized assistance to several companies, including, Dimension Therapeutics (NASDAQ: DMTX) and Basilea Pharmaceutica Ltd (SIX Swiss Exchange: BSLN). Prior to 2010, Mr. Thibault was Chief Financial Officer and Treasurer of deCODE genetics, Inc. (NASDAQ: DCGN), and a director at PricewaterhouseCoopers LLP. Mr. Thibault is a C.P.A. and received his B.S. in Accountancy from Bentley College.



*Louis A. Matis, Ph.D.* Louis A. Matis was appointed Senior Vice President and Chief Development Officer in August 2015. Prior to joining Pieris, Dr. Matis served since June 2011 as Executive Director, Strategic Evaluation at Alexion Pharmaceuticals, where he also served from 1993 to 2000, during which time he advanced to the position of Chief Scientific Officer and had a leading role in discovering the first-inclass complement inhibitor monoclonal antibody Soliris (eculizumab). Before re-joining Alexion in 2011, Dr. Matis served as Chief Executive Officer of CGI Pharmaceuticals, Inc. from 2000 to 2006, and of the Immune Tolerance Institute from 2007 to 2010. From 1977 until joining Alexion in 1993, Dr. Matis held senior research and clinical positions at the National Cancer Institute (the NCI), National Institutes of Health and the FDA Center for Biologics Evaluation and Research. Dr. Matis received a B.A. from Amherst College, an M.D. from the University of Pennsylvania, Perelman School of Medicine, and his clinical training in Internal Medicine at the University of Chicago Hospitals and Clinics, and in Medical Oncology at the NCI. Dr. Matis is the author of over 120 publications in major scientific and medical journals and is a co-inventor on multiple patents.

*Claude Knopf.* Mr. Claude Knopf joined Pieris as Chief Business Officer in December 2016 bringing to Pieris a demonstrable track record of success in strategy, corporate development, licensing, alliance management, marketing and sales spanning more than two decades. Prior to joining Pieris, Mr. Knopf was Senior Vice President, Global Head Business Development & Licensing and Mergers & Acquisitions for Baxalta (spin off of formerly Baxter Bioscience) and 2 years at Baxter where he was a Sr. VP and Global Head Business Development and Licensing BioScience. Prior to Baxter he spent over 12 years in Business Development and Alliance Management at Novartis in positions of increasing responsibility. Mr. Knopf began his career in Pharmaceuticals at Merck Sharp & Dohme where he held positions in finance, sales and marketing. Mr. Knopf earned a DEUG in Economics from Université Louis Pasteur, Strasbourg, a BA in Economics from Manchester College and a Master of International Business Studies from the University of South Carolina's Moore School of Business.

*Chau Khuong*. Mr. Khuong joined the Board of Directors of Pieris effective upon the closing of the Acquisition and has served on the supervisory board of Pieris GmbH since May 2014. Mr. Khuong has worked at OrbiMed Advisors LLC since 2003 and is a Private Equity Partner. Mr. Khuong gained experience in start-up operations and business development at Veritas Medicine, Inc. and in basic science research at the Yale School of Medicine and at Massachusetts General Hospital. He currently serves as a director of several public and private companies, including Aerpio Therapeutics, Inspire Medical Systems, Nabriva Therapeutics AG (NASDAQ: NBVR), NextCure, Inc., ReViral Ltd., Synlogic, and Graybug, Inc. Mr. Khuong holds a B.S. in molecular, cellular and developmental biology with concentration in biotechnology and an MPH with concentration in infectious diseases, both from Yale University. We believe that Mr. Khuong adds value to our Board of Directors due to his experience as an investor, particularly with respect to healthcare companies, and his broad life sciences industry knowledge. He also has extensive experience overseeing the operations and research and development of biotechnology companies.

*Michael Richman*. Mr. Richman joined the Board of Directors of Pieris in December 2014 and has served on the supervisory board of Pieris GmbH since October 2014. He is currently the President and Chief Executive Officer of NextCure, Inc. From 2008 through 2015 Mr. Richman was President and Chief Executive Officer of Amplimmune, Inc., a privately held biologics company focused on cancer and autoimmune diseases which was acquired by Astra Zeneca in 2013. From May 2007 through June 2008, he served as President and Chief Operating Officer of Amplimmune, Inc. Prior to such time, Mr. Richman has gained years of experience working in research, intellectual property and business development capacities in companies such as Chiron Corporation (now Novartis), MedImmune, Inc. (now Astra Zeneca) and MacroGenics. He is a member of the board of directors of Opexa Therapeutics, Inc., a public company, GenVec., a public company, Madison Vaccines, Inc., a private company, and was previously director of Cougar Biotechnology until its acquisition by Johnson & Johnson. Mr. Richman obtained his B.S. in genetics/molecular biology at the University of California at Davis and his M.S.B.A. in international business at San Francisco State University. We believe that Mr. Richman adds value to our Board of Directors due to his extensive experience in mergers and acquisitions, business

development and strategic planning for life science companies, as well as executive leadership and management experience.

Jean-Pierre Bizzari, M.D. Dr. Bizzari joined the Board of Directors of Pieris in May 2015. Dr. Bizzari served as Executive Vice-President, Group Head, Clinical Oncology Development at Celgene Corporation, a role he held from October 2008 until his retirement in December 2015. In this position, Dr. Bizzari was responsible for Celgene's clinical development and operations-statistics teams across the U.S., Europe and Asia/Japan, and has overseen the development and approval of a number of leading oncology products including REVLIMID® (lenalidomide), VIDAZA® (azacitidine), ISTODAX® (romidepsin) and ABRAXANE (nab-paclitaxel). In addition, he was Chairman of Celgene's hematology oncology development committee and a member of the company's management committee. Prior to his role at Celgene and from 2004 to 2008, Dr. Bizzari was the Vice President, Clinical Oncology Development for Sanofi-Aventis where he oversaw the approval of Eloxatin (oxaliplatin), Taxotere® (docetaxel) and Elitek (rasburicase). From 2002 to 2004, he was Vice President, Clinical Development Oncology for Sanofi-Synthelabo and from 1993 to 2002 served in the same role for Rhône-Poulenc Rorer (Aventis). Dr. Bizzari is a member of the Scientific Advisory Board of France's National Cancer Institute and a board member of the EORTC. He is also currently a member of the board of directors of Halozyme Therapeutics, Inc., Transgene SA, iTeos Therapeutics SA, Onxeo SA and Nordic Nanovector ASA. Mr. Bizzari also served as a member of the board of directors of Celator Pharmaceuticals, Inc. from March 2015 until its merger with Jazz Pharmaceuticals plc in July 2106. Dr. Bizzari received his medical degree from the University of Nice (France) and is an oncologist, having trained at La Pitié-Salpêtrière Hospital in Paris, followed by training at the Ontario Cancer Institute and McGill Cancer Center. We believe that Dr. Bizzari adds value to our Board of Directors based on his considerable experience in the pharmaceutical industry and his insight on clinical, regulatory and commercial aspects of drug development, particularly in oncology and global drug approval strategy.

*Steven Prelack.* Mr. Prelack joined the Board of Directors of Pieris in December 2014. Mr. Prelack is the Senior Vice President and Chief Operating Officer of VetCor, which owns and operates veterinary hospitals across the United States, and has served in this position since June 2012. Prior to that time and since May 2010, Mr. Prelack served at VetCor as Senior Vice President of Operations and as Chief Financial Officer. From 2001 until May 2010, he was the Senior Vice President, Chief Financial Officer and Treasurer of VelQuest Corporation, a provider of automated compliance software solutions for the pharmaceutical industry. He is currently a director and audit committee chair of Galectin Therapeutics, Inc., a publicly traded clinical-stage biotechnology company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Mr. Prelack also previously served as director and audit committee chair for BioVex Group, Inc., a clinical-stage biotechnology company focused on the development and future commercialization of targeted treatments for cancer and the prevention of infectious disease, which was sold to Amgen in 2011, and as a director of VelQuest Corporation, OPCAT, Inc. and Foodsafe Solutions, Inc. Mr. Prelack is a Certified Public Accountant, received a B.B.A. degree from the University of Massachusetts at Amherst in 1979 and is a member of the National Association of Corporate Directors. We believe that Mr. Prelack adds value to our Board of Directors due to his extensive executive leadership experience, director experience within the biotechnology sector and his many years serving in senior financial and operational management roles.

*Julian Adams, Ph.D.* Julian Adams, Ph.D., joined the Board of Directors of Pieris in July 2016. Dr. Adams has served as the President of Research & Development of Infinity since October 2007 and also served as its Chief Scientific Officer from September 2006 until May 2010. Prior to joining Infinity in 2003, Dr. Adams served as Senior Vice President, Drug Discovery and Development at Millennium Pharmaceuticals, Inc. from 1999 to 2001, where he led the development of bortezomib, also known as Velcade. Dr. Adams served as Senior Vice President, Research and Development at LeukoSite Inc., a private biopharmaceutical company, from July 1999 until its acquisition by Millennium Pharmaceuticals, Inc. in December 1999. Dr. Adams also served as a director and Executive Vice President of Research and Development at ProScript, Inc., a private biopharmaceutical company, from 1994 until its acquisition by LeukoSite Inc. in 1999. Prior to joining ProScript, Inc., Dr. Adams held a variety of positions with Boehringer Ingelheim, a private pharmaceutical company, and Merck & Co., Inc., a publicly traded pharmaceutical company. Dr. Adams served as a director of Aileron Therapeutics, Inc., a privately held biopharmaceutical company, from 2011 and to 2013, a director of Warp Drive Bio, LLC, a privately held life sciences company, since 2013, and a director of the Princess Margaret Cancer

Foundation since November 2014. Dr. Adams received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry. We believe that Dr. Adams adds value to our Board of Directors based on his considerable experience in the pharmaceutical industry and his experience as an executive of successful companies, both public and private, in the life sciences industry.

*Christopher Kiritsy*. Christopher Kiritsy joined the Board of Directors of Pieris in September 2016. Mr. Kiritsy is a co-founder of Arisaph Pharmaceuticals, Inc. ("Arisaph") and has served as Arisaph's President and Chief Executive Officer since 2005. Prior to Arisaph, Mr. Kiritsy served as Executive Vice President, Corporate Development and Chief Financial Officer of Kos Pharmaceuticals, Inc., where he played a key operating role in building the company from start-up to highly profitable, publicly traded, commercial company. During his 10-year tenure at Kos, Mr. Kiritsy spearheaded more than 10 major corporate development transactions and raised approximately \$500 million in public equity, including Kos's initial public offering. Kos was acquired by Abbott Laboratories for \$3.7 billion in 2016. Mr. Kiritsy is a seasoned entrepreneur, who possesses more than 20 years of business and technical experience, previously holding senior management positions in R&D, business development and finance. We believe that Mr. Kiritsy adds value to our Board of Directors based on his considerable experience in the pharmaceutical industry and his expertise in corporate development.

#### **Term of Office of Directors**

We currently have authorized seven directors. In accordance with our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

- the Class I director are Jean-Pierre Bizzari, Julian Adams, and Christopher Kiritsy and their terms will expire at the annual meeting of stockholders to be held in 2018;
- the Class II directors are Chau Khuong and Steven Prelack, and their terms will expire at the annual meeting of stockholders to be held in 2019; and
- the Class III directors are Stephen S. Yoder and Michael Richman, and their terms will expire at the annual meeting of stockholders to be held in 2017.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that each class will consist of approximately one-third of the directors.

#### **Family Relationships**

There are no family relationships among any of our current or former directors or executive officers.

#### **Involvement in Certain Legal Proceedings**

None of our directors, executive officers, significant employees, promoters or control persons has been involved in any legal proceeding in the past 10 years that would require disclosure under Item 401(f) of Regulation S-K promulgated under the Securities Act.

#### Nominations to the Board of Directors

Director candidates are considered based upon various criteria, including without limitation their broad-based business and professional skills and experiences, expertise in or knowledge of the life sciences industry and ability to add perspectives relating to that industry, concern for the long-term interests of our stockholders, diversity, and personal integrity and judgment. Our Board of Directors has a critical role in guiding our strategic

direction and overseeing the strategy of our business, and accordingly, we seek to attract and retain highly qualified directors who have sufficient time to engage in the activities of our Board of Directors and to understand and enhance their knowledge of our industry and business plans.

#### **Committees of the Board of Directors**

Our board has established three standing committees—audit, compensation, and nominating and corporate governance—each of which operates under a charter that has been approved by our board. Our board has determined that all of the members of each of the board's three standing committees are independent as defined under the rules of the NASDAQ Capital Market. In addition, all members of the audit committee meet the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

#### Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- · evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review
  of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board any changes to such investment policy;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Steven Prelack, Chau Khuong and Christopher Kiritsy. Steven Prelack serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Capital Market. Our board of directors has determined that Steven Prelack is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations.

#### Compensation Committee

Our compensation committee reviews and approves policies relating to compensation of our officers and directors and oversees our overall compensation structure, policies and programs. The compensation committee reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer

and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves the issuance of stock options and other awards under our equity plan. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Michael Richman, Christopher Kiritsy and Chau Khuong. Michael Richman serves as the chairperson of the committee.

#### Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board's responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors.

The members of our nominating and corporate governance committee are Jean-Pierre Bizzari, Julian Adams and Michael Richman. Dr. Bizzari serves as the chairperson of the committee.

#### SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires directors, executive officers, and persons owning more than 10 percent of a Company's class of equity securities registered under Section 12 of the Exchange Act to file reports on a timely basis on the initiation of their status as a reporting person and any changes with respect to their beneficial ownership of such equity securities with the SEC. Executive officers, directors and greater than 10 percent stockholders are required by SEC regulations to furnish those companies copies of all Section 16(a) forms they file.

Our records reflect all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis except for the following Forms 4 which were inadvertently filed late: Form 4 of Chau Khuong filed on August 1, 2016 reporting a stock option award and Form 4 of Michael Richman filed on August 1, 2016 reporting a stock option award.

# CODE OF CONDUCT AND ETHICS

We have adopted a Code of Ethics and Whistler Blower Policy that applies to all of our employees, including our chief executive officer and acting chief financial and accounting officer. The text of the code of conduct and ethics is posted on our website at www.pieris.com, is filed as an exhibit hereto, and will be made available to stockholders without charge, upon request, in writing to the Corporate Secretary at Pieris Pharmaceuticals, Inc., 255 State St. 9th Floor, Boston, MA 02109. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the rules of The NASDAQ Stock Market.

# Item 11. EXECUTIVE COMPENSATION

The following table summarizes the compensation earned in each of our fiscal years ended December 31, 2016 and 2015 by our named executive officers, which consisted of our principal executive officer and our two next most highly compensated executive officers who earned more than \$100,000 during the fiscal year ended December 31, 2016 and were serving as executive officers as of such date. We refer to the executive officers listed below as the Named Executive Officers.

#### **Summary Compensation Table**

				Option Awards (\$)	All other compensation	
Name and Principal Position	Year	Salary	Bonus (\$)	(2)	(\$)	Total
Stephen S. Yoder	2016	\$415,000	\$180,000	\$ 484,740	\$ 10,600(5)	\$1,090,340
Chief Executive Officer	2015(1)	\$375,000	\$150,000	\$ —	\$ 7,370(3)	\$ 532,370
Darlene Deptula-Hicks(4)	2016	\$300,000	\$120,000	\$ —	\$ 10,600(5)	\$ 430,600
Former Chief Financial Officer	2015	\$100,000	\$ 40,000	\$ 812,623	\$ 3,013(5)	\$ 955,636
Louis Matis	2016	\$350,000	\$140,000	\$ —	\$ —	\$ 490,000
Chief Development Officer	2015	\$131,250	\$140,000	\$1,066,220	\$ —	\$1,337,470

 Mr. Yoder's 2015 salary was paid in euros from January 1, 2015 through June 30, 2015 as he was a resident of Germany at the time. Pieris converted each euro denominated amount into U.S. dollars by multiplying the euro amount by the noon buying rate of €1.00 to U.S. \$1.0906 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2015. From the period of July 1, 2015 through December 31, 2015, Mr. Yoder's salary was paid in U.S. dollars.

(2) These amounts represent the aggregate grant date fair value for the option awards granted during the fiscal years presented, determined in accordance with FASB ASC Topic 718. All awards are recognized in expense over the service period.

(3) Represents compensation paid for a monthly car allowance.

(4) Ms. Deptula-Hicks resigned from the Company effective February 7, 2017.

(5) Represents compensation paid for a 401(k) employer contribution.

#### Narrative Disclosure to Summary Compensation Table

#### Stephen S. Yoder, Chief Executive Officer

Stephen S. Yoder serves as our President and Chief Executive Officer pursuant to an employment agreement dated December 17, 2014, or the Yoder Employment Agreement. The Yoder Employment Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Mr. Yoder resigns he shall provide us with at least 90 days' prior written notice. Pursuant to this agreement, Mr. Yoder's annual base salary was increased to \$375,000, effective as of the closing of the Acquisition. In addition, Mr. Yoder is eligible to receive an annual discretionary bonus of up to 40% of Mr. Yoder's then-effective annual base salary, based upon achievement of individual and corporate performance objectives as determined by the Board of Directors or a committee thereof.

On the effective date of the Acquisition, Mr. Yoder was granted a stock option to purchase 1,280,000 shares of our common stock with the exercise price being the fair market value at the time of grant. The option is subject to and governed by the terms of the Pieris Plan and a stock option agreement, which stock option agreement provides for a ten year term, and that (i) 25% of the option vested immediately upon grant and (ii) 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant, subject to Mr. Yoder's continued employment.

Pursuant to the Yoder Employment Agreement, Mr. Yoder is prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, unless approved by the Chairman of the Board of Directors, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Mr. Yoder to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain noncompete provisions extending during the term of the agreement and one year thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Mr. Yoder also agreed to assign certain intellectual property rights to Pieris.

All compensation and benefits to be paid to Mr. Yoder pursuant to the Yoder Employment Agreement other than the equity awards shall be paid to Mr. Yoder through the terms and conditions of the Yoder AG Agreement with Pieris GmbH, as amended and restated, for so long as Mr. Yoder remains employed at Pieris. Upon termination of the Yoder AG Agreement provided that the Yoder Employment Agreement is still in effect, all compensation shall be paid by Pieris.

#### Termination for Any Reason

Upon termination of Mr. Yoder for any reason, Mr. Yoder will receive all earned but unpaid salary, any accrued vacation time, any vested benefits he may have under any employee benefit plan and any unpaid expense reimbursement accrued through the date of termination, or the Accrued Obligations.

#### Termination by us Without Cause or by Executive for Good Reason

If Mr. Yoder's employment is terminated (i) by us without cause or (ii) by him for good reason, then we must pay Mr. Yoder (i) the Accrued Obligations earned through the date of termination, (ii) a lump-sum payment comprised of (a) an amount equal to 12 months of his base salary at the time of his termination, and (b) a pro rata portion of the bonus for the year in which the termination occurs, based on year-to-date performance as determined by the Board of Directors, or a committee thereof, in its sole discretion, and (iii) an amount equal to his health insurance premium, paid directly or as a reimbursement to Mr. Yoder, for up to a maximum of 12 months. Payments under items (i)—(iii) above are sometimes referred to in this section as Severance. All unvested equity awards held by Mr. Yoder will immediately vest in full and become exercisable following termination and any forfeiture restrictions will immediately lapse. The Severance and acceleration of any unvested options is expressly conditioned on Mr. Yoder executing and delivering to Pieris a release of claims.

#### Darlene Deptula-Hicks, Former Chief Financial Officer

Ms. Deptula-Hicks resigned from the Company in February 2017. In August 2015, we entered into an employment agreement with Ms. Deptula-Hicks, pursuant to which we agreed to employ Ms. Deptula-Hicks on an at-will basis. Ms. Deptula-Hicks's 2016 base salary was \$300,000 pursuant to the terms of our employment agreement with her. Pursuant to the terms of his employment agreement, she was eligible for an annual bonus of up to 40% of her base salary, as determined by our Board in its sole discretion on the achievement of performance goals determined by our Chief Executive Officer in consultation with the Board. Ms. Deptula-Hicks is bound by the terms of agreements covering non-solicitation, non-competition, confidential information and inventions assignment, which, among other things, prevent her from competing with us for a specified time after cessation of employment.

In connection with Ms. Deptula-Hicks's resignation, we entered into a separation agreement with Ms. Deptula-Hicks in February 2017. Pursuant to the terms and conditions of the separation agreement, Ms. Deptula-Hicks is entitled to receive twelve months of her gross biweekly salary, to be paid pursuant to our normal payroll

practices, continuation of health benefits for twelve months and payment of her 2016 annual discretionary bonus in the amount of \$120,000.

In addition, the separation agreement provides that the vesting of twenty-five percent (25%) of the unvested portion of Ms. Deptula-Hicks's stock option award was accelerated and the exercise period of her stock option award was extended until February 7, 2018. The stock option award issued to Ms. Deptula-Hicks by the Company shall be exercised, to the extent vested as of her separation date (including the acceleration described above), by way of a "net exercise" method whereby the Company shall withhold from the delivery of the shares of the Company's common stock, par value \$0.001 per share (the "Common Stock"), such number of shares of common stock having a fair market value on the exercise date equal to the aggregate exercise price for the shares of common stock for which each of the stock options is exercised. Ms. Deptula-Hicks has agreed not to offer, sell, contract to sell, pledge, grant any option to purchase or otherwise dispose of more than 50,000 shares of common stock issued pursuant to such option exercise per each rolling thirty day period.

### Louis Matis, Chief Development Officer

Dr. Louis Matis serves as our Senior Vice President and Chief Development Officer pursuant to an employment agreement dated July 20, 2015, or the Matis Employment Agreement. The Matis Employment Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Dr. Matis resigns, he shall provide us with at least 90 days' written notice. Pursuant to this agreement, Dr. Matis receives a base salary of \$350,000 and is eligible to receive an annual discretionary bonus award of up to 40% of his then-current base salary, based upon the achievement of specific individual and/or Company-wide performance goals as determined by the Board or a committee of the Board in its sole discretion.

Dr. Matis is entitled to participate in any employee benefit programs, plans and practices on the same terms as other salaried employees on a basis consistent with the participation of other senior executive officers. In connection with his employment, Dr. Matis was granted an inducement stock option to purchase 500,000 shares of our common stock with the exercise price being the fair market value at the time of grant. The option is subject to and governed by a stock option agreement, which provides for a ten year term, and that (i) 25% of the option vests on the one-year anniversary of Dr. Matis's start date and (ii) 75% of the option shall vest ratably in equal installments each quarter thereafter, subject to Dr. Matis's continued employment.

Under the Matis Employment Agreement, Dr. Matis is prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, unless approved by the Chief Executive Officer, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Dr. Matis to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain noncompete provisions extending during the term of the agreement and one year thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Dr. Matis also agreed to assign certain intellectual property rights to Pieris.

#### Termination for Any Reason

Upon termination of Dr. Matis for any reason, Dr. Matis will be entitled to receive all earned but unpaid salary, any accrued vacation time, any vested benefits he may have under any employee benefit plan and any unpaid expense reimbursement accrued through the date of termination.

#### Termination by us Without Cause or by Executive for Good Reason

If Dr. Matis's employment is terminated (i) by us without cause or (ii) by him for good reason, then Dr. Matis will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount, pro-rated

based on the total number of days elapsed in the calendar year as of the termination date if, as of the date of termination, the Company and Ms. Deptula-Hicks were "on target" to achieve all applicable performance goals and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In addition, outstanding equity awards held by Dr. Matis shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Matis Employment Agreement, and any forfeiture restrictions shall immediately lapse with respect to 75% of the then-unvested equity awards.

### Potential Payments upon Termination or Change in Control

#### Stephen S. Yoder, Chief Executive Officer

Under the Yoder Employment Agreement, if Mr. Yoder's employment is terminated (i) by us without cause or (ii) by Mr. Yoder for good reason within 12 months following a change in control, and Mr. Yoder executes and delivers to Pieris a release of claims, then Mr. Yoder shall receive (i) the Accrued Obligations earned through the date of termination, (ii) a lump-sum payment comprised of (a) an amount equal to 12 months of his base salary at the time of his termination, and (b) the target bonus for the year in which the termination occurs, and (iii) an amount equal to his health insurance premium, paid directly or as a reimbursement to Mr. Yoder, for up to a maximum of 12 months. All unvested equity awards will immediately vest in full and become exercisable following termination and any forfeiture restrictions will immediately lapse.

For purposes of the Yoder Employment Agreement, "cause" shall mean the occurrence of any of the following events, as determined by the Board of Directors or a committee designated by the Board of Directors, in its sole discretion: (i) Mr. Yoder's commission of any felony or any crime involving fraud, dishonesty, or moral turpitude under the laws of Germany, the United States or any state thereof; (ii) Mr. Yoder's attempted commission of, or participation in, a fraud against Pieris; (iii) Mr. Yoder's intentional, material violation of any contract or agreement between Mr. Yoder and Pieris or of any statutory duty owed to Pieris; (iv) Mr. Yoder's unauthorized use or disclosure of Pieris' confidential information or trade secrets; or (v) Mr. Yoder's gross misconduct.

For purposes of the Yoder Employment Agreement, "good reason" means Mr. Yoder's resignation from all positions he then holds with Pieris if (i) (a) there is a material diminution in Mr. Yoder's duties and responsibilities with Pieris; (b) there is a material reduction of Mr. Yoder's base salary; provided, however, that a material reduction in Mr. Yoder's base salary pursuant to a salary reduction program affecting all or substantially all of the employees of Pieris and that does not adversely affect Mr. Yoder to a greater extent than other similarly situated employees shall not constitute good reason; or (c) Mr. Yoder is required to relocate Mr. Yoder's primary work location to a facility or location that would increase Mr. Yoder's one-way commute distance by more than 50 miles from Mr. Yoder's primary work location as of immediately prior to such change, (ii) Mr. Yoder provides written notice outlining such conditions, acts or omissions to Pieris within 30 days immediately following such material change or reduction, (iii) such material change or reduction is not remedied by Pieris within 30 days following Pieris' receipt of such written notice and (iv) Mr. Yoder's resignation is effective not later than 30 days after the expiration of such 30 day cure period.

For purposes of the Yoder Employment Agreement, a "change in control" shall be deemed to occur (i) when any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of Pieris representing 50% or more of the total voting power represented by Pieris' then outstanding voting securities (excluding for this purpose any such voting securities held by the Pieris or its affiliates or by any employee benefit plan of Pieris) pursuant to a transaction or a series of related transactions which the Board of Directors does not approve; or (ii) a merger or consolidation of Pieris outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) more than 50% of the total voting

power represented by the voting securities of Pieris or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or (iii) the sale or disposition by Pieris of all or substantially all of its assets in a transaction requiring stockholder approval.

#### Louis Matis, Chief Development Officer

If, in connection with a change of control of Pieris, Pieris terminates Dr. Matis's employment without cause or Dr. Matis terminates his employment for good reason, he will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount for the year of termination and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In the case of such a termination in connection with a change in control, outstanding equity awards held by Dr. Matis shall automatically become vested and if, applicable, exercisable and all forfeiture restrictions shall immediately lapse.

For purposes of the Matis Employment Agreement, "Good Reason" means the executive's resignation from all positions he or she then holds with the Company if (i) (A) there is a material diminution in the executive's duties and responsibilities with the Company or in job title; (B) there is a material reduction of the executive's base salary; provided, however, that a material reduction in the executive's base salary pursuant to a salary reduction program affecting all or substantially all of the employees of the Company and that does not adversely affect the executive to a greater extent than other similarly situated employees shall not constitute Good Reason; or (C) the executive is required to relocate the executive's primary work location to a facility or location that would increase the executive's one-way commute distance by more than fifty (50) miles from the executive's primary work location as of immediately prior to such change, (ii) the executive provides written notice outlining such conditions, acts or omissions to the Company within thirty (30) days immediately following such material change or reduction, (iii) such material change or reduction is not remedied by the Company within thirty (30) days after the expiration of such thirty (30) day cure period.

#### **2016 Bonus Payments**

On February 3, 2017, our Compensation Committee approved a discretionary cash bonus payments to (i) Mr. Yoder in the amount of \$180,000, which was equal to his target bonus amount, (ii) Dr. Matis in the amount of \$140,000, which was equal to his target bonus amount and (iii) Ms. Deptula-Hicks in the amount of \$120,000, which was equal to her target bonus amount.

#### **Outstanding Equity Awards at Fiscal Year-End**

The table below summarizes the aggregate stock and option awards held by our named executive officers as of December 31, 2016.

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	1	n exercise ice (\$)	Option expiration date
Stephen S. Yoder	960,000(1)	320,000(1)	\$	2.00	12/17/2024
Chief Executive Officer, President	—(2)	492,000(2)	\$	1.52	02/12/2026
Darlene Deptula-Hicks Former Chief Financial Officer	159,961	290,039(3)	\$	2.80	9/1/2025
Louis Matis Chief Development Officer	156,250	343,750(4)	\$	3.36	8/17/2025

(1) The option award has a grant date of December 17, 2014 and vests pursuant to the following schedule: 25% of the option vested immediately upon grant on December 17, 2014 and 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant.

- (2) The option award has a grant date of February 12, 2016 and vests pursuant to the following schedule: 25% of the option vests on the one-year anniversary of the grant date and 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant.
- (3) This option award vested with respect to 25% of the unvested shares on February 7, 2017 in connection with the separation agreement with Ms. Deptula-Hicks and the remainder ceased to vest. Ms. Deptula-Hicks is entitled to exercise these options until February 7, 2018.
- (4) The option award has a grant date of August 17, 2015 and vests pursuant to the following schedule: 25% of the option vests on the oneyear anniversary of the grant date and 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant.

#### **Description of Pieris Stock Option Plans**

In December 2014, our Board of Directors and stockholders adopted the 2014 Employee, Director and Consultant Equity Incentive Plan, or the 2014 Plan, which became effective upon closing of the Acquisition. In connection with the approval of the 2016 Plan (as defined below), the 2014 Plan was cancelled in 2016 and no options are available for future issuance under the 2014 Plan.

In June 2016, our stockholders adopted the 2016 Employee, Director and Consultant Equity Incentive Plan, or the 2016 Plan. The 2016 Plan was intended to replace the 2014 Plan, which was terminated as the Company received stockholder approval of the 2016 Plan. The 2016 Plan authorizes the issuance of up to 3,750,000 shares of our common stock pursuant to awards to be granted under the 2016 Plan. In addition, the 2016 Plan allowed additional shares to be issued if awards outstanding under the 2014 Plan were cancelled or expired on or after June 28, 2016. Generally, shares of common stock reserved for awards under the 2016 Plan that lapse or are canceled will be added back to the share reserve available for future awards. However, shares of common stock tendered in payment for an award or shares of common stock withheld for taxes will not be available again for grant. The 2016 Plan provides that no participant may receive awards for more than 1,500,000 shares of common stock in any fiscal year.

*Eligibility*. The 2016 Plan allows us, under the direction of our Compensation Committee, to make grants of stock options, restricted and unrestricted stock awards and other stock-based awards to employees, consultants and directors who, in the opinion of the Compensation Committee, are in a position to make a significant contribution to our long-term success. The purpose of these awards is to attract and retain key individuals, further align employee and stockholder interests, and to closely link compensation with Company performance. The 2016 Plan provides an essential component of the total compensation package, reflecting the importance that we place on aligning the interests of key individuals with those of our stockholders. All employees, directors and consultants of the Company and its affiliates are eligible to participate in the 2016 Plan.

*Performance Goals*. In order for the Company to have the ability to grant awards under the 2016 Plan that qualify as "performance-based compensation" under Section 162(m) of the Code, the 2016 Plan provides that our Compensation Committee may require that the vesting of certain 2016 plan awards (other than stock options and SARs) be conditioned on the satisfaction of performance criteria related to objectives of the Company, an affiliate of the Company or a division or strategic business unit of the Company in which the relevant participant is employed, such as: (i) pre-tax income or after-tax income; (ii) income or earnings including operating income, earnings before or after taxes, interest, depreciation, amortization, and/or extraordinary or special items; (iii) net income excluding amortization of intangible assets, depreciation and impairment of goodwill and intangible assets and/or excluding charges attributable to the adoption of new accounting pronouncements; (iv) earnings or book value per share (basic or diluted); (v) return on assets (gross or net), return on investment, return on capital, return on invested capital or return on equity; (vi) return on revenues; (vii) cash flow, free cash flow, cash flow return on investment (discounted or otherwise), net cash provided by operations, or cash flow in excess of cost of capital; (viii) economic value created; (ix) operating margin or profit margin; (x) stock price or total shareholder

return; (xi) income or earnings from continuing operations; (xii) cost targets, reductions and savings, expense management, productivity and efficiencies; (xiii) operational objectives, consisting of one or more objectives based on achieving progress in research and development programs or achieving regulatory milestones related to development and or approval of products; and (xiv) strategic business criteria, consisting of one or more objectives based on meeting specified market penetration or market share of one or more products or customers, geographic business expansion, customer satisfaction, employee satisfaction, human resources management, supervision of litigation, information technology, and goals relating to acquisitions, divestitures, joint ventures and similar transactions. As discussed above, if we determine to make awards under the 2016 Plan subject to the attainment of these performance goals, the Compensation Committee intends that compensation paid under the 2016 Plan will not be subject to the deductibility limitation imposed under Section 162(m) of the Code.

*Stock Options.* Stock options granted under the 2016 Plan may either be incentive stock options, which are intended to satisfy the requirements of Section 422 of the Code, or non-qualified stock options, which are not intended to meet those requirements. Incentive stock options may be granted to employees of the Company and its affiliates. Non-qualified stock options may be granted to employees, directors and consultants of the Company and its affiliates. The exercise price of a stock option may not be less than 100% of the fair market value of our common stock on the date of grant and may not have a term longer than ten years. However, if an incentive stock option is granted to an individual who owns more than 10% of the combined voting power of all classes of our capital stock, the exercise price may not be less than 110% of the fair market value of our common stock on the date of grant and may not have a term longer than the term of the incentive stock option may not be longer than five years. Non-qualified options may not have a term longer than ten years.

Award agreements for stock options include rules for exercise of the stock options after termination of service. Options may not be exercised unless they are vested, and no option may be exercised after the end of the term set forth in the award agreement. Generally, stock options will be exercisable for three months after termination of service for any reason other than death or total and permanent disability, and for 12 months after termination of service on account of death or total and permanent disability.

*Restricted Stock*. Restricted stock is common stock that is subject to restrictions, including a prohibition against transfer and a substantial risk of forfeiture, until the end of a "restricted period" during which the grantee must satisfy certain vesting conditions. If the grantee does not satisfy the vesting conditions by the end of the restricted period, the restricted stock is forfeited.

During the restricted period, the holder of restricted stock has the rights and privileges of a regular stockholder, except that the restrictions set forth in the applicable award agreement apply. For example, the holder of restricted stock may vote and receive dividends on the restricted shares; but he or she may not sell the shares until the restrictions are lifted.

*Other Stock-Based Awards*. The 2016 Plan also authorizes the grant of other types of stock-based compensation including, but not limited to phantom stock awards, and stock unit awards. Our Compensation Committee may award such stock-based awards subject to such conditions and restrictions as it may determine. These conditions and restrictions may include continued employment with us through a specified restricted period.

*Termination of Service.* Unless otherwise provided by the administrator or in an award agreement, upon a termination of a participant's service, all unvested options then held by the participant will terminate and all other unvested awards will be forfeited.

*Plan Administration*. In accordance with the terms of the 2016 Plan, our Board of Directors has authorized our Compensation Committee to administer the 2016 Plan. In accordance with the provisions of the 2016 Plan, our Compensation Committee determines the terms of awards, including:

• which employees, directors and consultants will be granted awards;

- the number of shares subject to each award;
- the vesting provisions of each award;
- · the termination or cancellation provisions applicable to awards; and
- all other terms and conditions upon which each award may be granted in accordance with the 2016 Plan.

In addition, our Compensation Committee may, in its discretion, amend any term or condition of an outstanding award provided (i) such term or condition as amended is permitted by the 2016 Plan, and (ii) any such amendment shall be made only with the consent of the participant to whom such award was made, if the amendment is adverse to the participant; and provided, further, that, without the prior approval of our stockholders, options will not be repriced, replaced or regranted through cancellation or by lowering the exercise price of a previously granted option and will not be exchanged for cash.

*Stock Dividends and Stock Splits*. If our common stock shall be subdivided or combined into a greater or smaller number of shares or if we issue any shares of common stock as a stock dividend, the number of shares of our common stock deliverable upon exercise of an option issued or upon issuance of an award shall be appropriately increased or decreased proportionately, and appropriate adjustments shall be made in the purchase price per share to reflect such subdivision, combination or stock dividend.

*Corporate Transactions*. Upon a merger or other reorganization event, our Board of Directors, may, in its sole discretion, take any one or more of the following actions pursuant to the 2016 Plan, as to some or all outstanding awards:

- provide that outstanding options will be assumed or substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;
- provide that the outstanding options must be exercised within a certain number of days, either to the extent the options are then exercisable, or at the administrator's discretion, any such options being made partially or fully exercisable;
- terminate outstanding options in exchange for payment of an amount equal to the difference between (a) the consideration payable upon consummation of the corporate transaction to a holder of the number of shares into which such option would have been exercisable to the extent then exercisable (or, in the administrator's discretion, any such options being made partially or fully exercisable) and (b) the aggregate exercise price of those options;
- provide that outstanding awards will be assumed or substituted for shares of the successor corporation, become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the corporate transaction; and
- terminate outstanding stock grants in exchange for payment of any amount equal to the consideration payable upon consummation of the corporate transaction to a holder of the same number of shares comprising the stock grant, to the extent the stock grant is no longer subject to any forfeiture or repurchase rights (or, at the administrator's discretion, all forfeiture and repurchase rights being waived upon the corporate transaction).

Amendment and Termination. The 2016 Plan may be amended by our stockholders. It may also be amended by our Board of Directors, provided that any amendment approved by our Board of Directors which is of a scope that requires stockholder approval as required by the rules of the Nasdaq Stock Market, in order to ensure favorable federal income tax treatment for any incentive stock options under Code Section 422, or for any other reason is subject to obtaining such stockholder approval. However, no such action may adversely affect any rights under any outstanding award without the holder's consent.



Duration of Plan. The 2016 Plan will expire by its terms on April 8, 2026.

The 2016 Plan also includes the following changes from the 2014 Plan:

- *No Evergreen Share Increase*—eliminates the "evergreen" feature pursuant to which the number of shares reserved for issuance under the 2014 Plan is automatically replenished each year;
- Authorizes Performance Awards in compliance with Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code")—allows us to maximize corporate deductibility of executive compensation to the extent that it may be desirable to do so as discussed in more detail below,
- Eliminate Repricing without Stockholder Approval—provides that our board of directors may not, without stockholder approval, reduce the exercise price of a stock option or stock appreciation right, cancel any outstanding stock option or stock appreciation right in exchange for a replacement stock option or stock appreciation right having a lower exercise or strike price or for any other stock award or for cash, or otherwise "reprice" a stock option or stock appreciation right as defined in the stockholder approval rules of The NASDAQ Stock Market or under generally accepted accounting principles.

As of the date of this report, options to purchase 548,813 shares of our common stock have been issued under the 2016 Plan to our executive officers and directors, and options to purchase 166,500 shares have been issued under the 2016 Plan to other employees and consultants. For additional information, see "Item 11. Executive Compensation—Director Compensation" and "Item 11. Executive Compensation—Employment Agreements with our Chief Executive Officer." As a result of such grants, 3,124,687 shares of our common stock remain available for future issuances under the 2016 Plan.

#### **Director Compensation**

The table below summarizes all compensation earned by each of our non-employee directors for services performed during our fiscal year ended December 31, 2016. Mr. Yoder is not in the table below because he receives no separate compensation for his services as a director of our company, and all of the compensation earned by Mr. Yoder during our 2016 fiscal year as an executive officer of our company is reflected in the Summary Compensation Table above.

Name	Fees earned or paid in cash (\$)	Stock awards (\$)	Option awards (\$)	Total (\$)
Chau Khuong (1)	\$ —	\$ —	\$61,279(7)	\$61,279
Michael Richman (2)	\$ —	\$ —	\$58,779(7)	\$58,779
Steven Prelack (3)	\$ 40,000	\$ —	\$20,030(7)	\$60,030
Jean-Pierre Bizzari (4)	\$ 28,750	\$ —	\$20,030(7)	\$48,780
Julian Adams (5)	\$ 28,750	\$ —	\$32,441(7)	\$61,191
Christopher Kiritsy (6)	\$ 37,500	\$ —	\$29,849(7)	\$67,349

(1) As of December 31, 2016, Chau Khuong held option awards for 109,258 shares at exercise prices ranging from \$1.59 to \$3.00.

(2) As of December 31, 2016, Michael Richman held option awards for 135,668 shares at exercise prices ranging from \$1.59 to \$3.00.

- (3) As of December 31, 2016, Steven Prelack held option awards for 50,000 shares at an exercise price ranging from \$1.59 to \$2.00.
- (4) As of December 31, 2016, Jean-Pierre Bizzari held option awards for 50,000 shares at an exercise price ranging from \$1.59to \$2.80.

(5) As of December 31, 2016, Julian Adams held option awards for 30,000 shares at an exercise price of \$1.73.

(6) As of December 31, 2016, Christopher Kiritsy held option awards for 30,000 shares at an exercise price of \$1.59.

(7) These amounts represent the aggregate grant date fair value of option awards granted to each director in fiscal year 2016 computed in accordance with FASB ASC Topic 718.

On January 11, 2015, our Board of Directors approved a director compensation policy applicable to our non-employee directors and the policy was amended in March 2017. This policy provides for annual cash compensation of \$35,000 for each non-employee member of our Board of Directors. In addition, the chairman the Board of Directors will receive additional annual compensation of \$25,000; the chair of our audit committee will receive additional annual cash compensation of \$15,000; the chair of our compensation committee will receive additional annual cash compensation of \$10,000; and the chair of our nominating and corporate governance committee will receive additional annual cash compensation of \$7,500. The policy also provides for annual cash compensation of \$7,500 for each of the members of our audit committee, \$5,000 for each of the members of our compensation committee and \$3,750 for each of the members of our nominating and corporate governance committee.

In addition, the policy provides that each of our non-employee directors will be eligible to receive annual equity awards of 15,000 options, which amount was increased to 20,000 options for 2016, to purchase our common stock, and that upon appointment, new non-employee directors will be eligible to receive an equity award of 30,000 options to purchase our common stock. It is anticipated that all such equity awards will be granted under the Pieris Plan or any other equity compensation plan our Board of Directors and stockholders may approve and adopt in the future. The type of any such award, the amount of shares subject to the award, the vesting schedule and all other terms thereof will be subject to the discretion and approval of our Board of Directors on annual basis.

# Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

#### Security Ownership of Certain Beneficial Owners and Management

The following table sets forth the number of shares of our common stock beneficially owned as of March 15, 2017, by (i) each of our current directors and named executive officers, (ii) all executive officers and directors as a group, and (iii) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock. We have determined beneficial ownership in accordance with applicable rules of the SEC, which generally provide that beneficial ownership includes voting or investment power with respect to securities. Except as indicated by the footnotes to the table below, we believe, based on the information furnished to us, that the persons named in the table have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

The information set forth in the table below is based on 43,058,827 shares of our common stock issued and outstanding on of March 15, 2017. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other convertible securities held by that person that are currently exercisable or will be exercisable within 60 days after March 15, 2017. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as otherwise noted in the

footnotes below, the address for each person listed in the table below, solely for purposes of filings with the SEC, is c/o Pieris Pharmaceuticals, Inc., 225 State Street, 9th Floor, Boston, Massachusetts 02109.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5%+ Stockholders:		
OrbiMed Advisors LLC (1)	7,259,620	16.86%
Biotechnology Value Fund, L.P. (2)	4,573,142	9.99%
Tekla Capital Management LLC (3)	4,145,958	9.63%
Lombard Odier Asset Management (USA) Corp. (4)	2,422,930	5.63%
Directors and Named Executive Officers:		
Stephen S. Yoder (5)	1,199,750	2.71%
Michael Richman (6)	135,355	*
Chau Khuong (7)	117,071	*
Steven Prelack (8)	47,500	*
Jean-Pierre Bizzari (9)	55,000	*
Louis Matis (10)	197,500	*
Julian Adams (11)	27,500	*
Christopher Kiritsy (12)	27,500	*
All Current Directors and Executive Officers as a Group (9 persons) (13)	1,807,176	4.03%

#### \* Less than 1%.

- (1) This information is based solely on a Schedule 13D filed with the Securities and Exchange Commission on or about July 8, 2016. Includes 7,194,222 shares held of record by OrbiMed Private Investments III, LP, or OPI III, and 65,398 shares held of record by OrbiMed Associates III, LP, or Associates III. The address for OPI III and Associates III is 601 Lexington Avenue, 54th Floor, New York, New York. Shares of Pieris are directly owned by OPI III and Associates III. OrbiMed Advisors LLC, or Advisors, is the general partner of Associates III and the sole managing member of GP III and Samuel D. Isaly is the managing member of, and owner of a controlling interest in, Advisors. Accordingly, Advisors and Mr. Isaly share the power to direct the vote and disposition of the shares held by OPI III; Advisors, Mr. Isaly and GP III share the power to direct the vote and disposition of the shares sheld by Associates III. Advisors, pursuant to its authority as the sole managing member of GP III, which is the sole general partners of OPI III, and as the sole general partner of Associates III, may be deemed to indirectly beneficially own the shares of Common Stock held by OPI III and Associates III. GP III, pursuant to its authority as the general partner of OPI III, may be deemed to directly beneficially own the shares held by OPI III. Islay, pursuant to his authority as the general partner of Advisors and owner of a controlling interest in Advisors, pursuant to its limited liability company agreement, may be deemed to also indirectly beneficially own the shares attributable to Advisors.
- (2) This information is based solely on a Schedule 13G/A filed with the Securities and Exchange Commission on or about February 14, 2017 and includes (i) 1,854,768 shares of common stock and (ii) 2,718,374 shares of common stock issuable upon the conversion of Series A Preferred Stock. The address of the principal business and office of BVF Inc. and certain of its affiliates is 1 Sansome Street, 30th Floor, San Francisco, California, 94194. BVF Inc. and its related entities beneficially hold (i) 1,854,768 shares of Common Stock, (ii) 4,963 shares a Series A Convertible Preferred Stock, which is convertible into 4,963,000 shares of common stock, and (iii) warrants exercisable for 2,977,800 shares of common stock. The Series A Preferred Stock may not be converted and the warrants may not be exercised if, after such conversion or exercise, BVF Inc. and its affiliates would beneficially own more than 9.99% of the number of shares of common stock then issued and outstanding. As a result of the limitation in the previous sentence, (i) 2,244,626 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,800 shares of common stock issuable upon the conversion of Series A Preferred Stock and (ii) 2,977,80

or Partners, is the general partner of Biotechnology Value Fund, L.P., or BVF, and Biotechnology Value Fund II, L.P., or BVF II; Partners is the investment manager of Biotechnology Value Trading Fund OS LP, or Trading Fund OS, and is the sole member of BVF Partners OS Ltd, or Partners OS. BVF Inc. is the general partner of Partners, and Mark N. Lampert is a director and officer of BVF Inc. Partners OS disclaims beneficial ownership of the shares of common stock beneficially owned by Trading Fund OS. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares of common stock beneficially owned by BVF, BVF2, Trading Fund OS, and certain Partners management accounts.

- (3) This information is based solely on a Schedule 13G filed with the Securities and Exchange Commission on or about February 13, 2017. The address for Tekla Capital Management LLC is 100 Federal St., 19th Floor, Boston, MA 02110. Tekla Capital Management LLC ("TCM") is the beneficial owner of 4,145,958 shares of the Common Stock of Pieris as a result of acting as investment adviser to Tekla Healthcare Investors ("HQH"), Tekla Life Sciences Investors ("HQL") and Tekla Healthcare Opportunities Fund ("THQ"). Each of TCM and Daniel R. Olmstead, through his control of TCM, has sole power to dispose of the 4,145,958 shares beneficially owned by HQH, HQL and THQ. Neither TCM nor Daniel R. Olstead has the sole power to vote or direct the vote of the shares beneficially owned by HQH, HQL and THQ which power resides in each fund's Board of Trustees. TCM carries out the voting of the shares under written guidelines established by each fund's Board of Trustees.
- (4) This information is based solely on a Schedule 13G/A filed with the Securities and Exchange Commission on or about February 14, 2017. The address for Lombard Odier Asset Management (USA) Corp is 452 Fifth Avenue, 25th Floor, New York, New York, 10018. Lombard Odier Asset Management (USA) Corp serves as investment advisor for the shares held by 1798 Fundamental Strategies Master Fund and shares the power to dispose or direct the vote and the disposition of the shares held by 1798 Fundamental Strategies Master Fund.
- (5) Includes 6,000 shares of our common stock and 1,193,750 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (6) Includes 135,355 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (7) Includes 117,071 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (8) Includes 47,500 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (9) Includes 55,000 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (10) Includes 10,000 shares of our common stock and 187,500 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (11) Includes 27,500 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (12) Includes 27,500 shares issuable upon the exercise of options to purchase common stock, which are exercisable within 60 days of March 15, 2017.
- (13) See notes 5 through 12 above; also includes Claude Knopf and Lance Thibault, who are executive officers but not named executive officers.

#### Securities Authorized for Issuance under Equity Compensation Plans

### Equity Compensation Plan Information

The following table sets forth information as of December 31, 2016 with respect to compensation plans under which equity securities of the Company are authorized for issuance. For a description of the terms of the Pieris Plan, please see "Item 11. Executive Compensation—Description of Pieris Plan."

<u>Plan Category</u>	Number of securities to be issued upon exercise of outstanding options, warrants and rights	exerci outs options	ted-average se price of tanding s, warrants l rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders	4,440,376	\$	1.99	3,124,687
Equity compensation plans not approved by security holders	1,000,000	\$	2.41	
Total	5,440,376		_	3,124,687

#### Stock Option Agreement with Dr. Matis

Pursuant to a Stock Option Agreement with Dr. Matis, dated August 17, 2015, Dr. Matis was granted an option to purchase 500,000 shares of Common Stock at a price per share of \$3.36, as an inducement material to his entering into employment with us. The grant has a term of ten years and is subject to a vesting schedule of 4 years, with 25% of the shares vesting on August 17, 2016 and 6.25% of the shares vesting each quarter thereafter, subject to his continued employment with the Company.

#### Stock Option Agreement with Dr. Knopf

Pursuant to a Stock Option Agreement with Dr. Knopf, dated November 28, 2016, Dr. Knopf was granted an option to purchase 500,000 shares of Common Stock at a price per share of \$1.45, as an inducement material to his entering into employment with us. The grant has a term of ten years and is subject to a vesting schedule of 4 years, with 25% of the shares vesting on November 28, 2017 and 6.25% of the shares vesting each quarter thereafter, subject to his continued employment with the Company.

### Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

#### **Related Party Transactions**

### Pieris (Pieris Pharmaceuticals, Inc., formerly known as Marika Inc.)

Except as described below, in the fiscal years ended December 31, 2015 and December 31, 2016, there has not been, nor is there currently proposed, any transaction to which Pieris is or was a party in which the amount involved exceeds the lesser of \$120,000 and 1% of the average of its total assets at year-end for the last two completed fiscal years, and in which any of our current directors, executive officers, holders of more than 5% of any class of our voting securities or any of their respective affiliates or immediate family members, had, or will have, a direct or indirect material interest.

We have entered into indemnification agreements with each of our directors and executive officers. Each of those indemnification agreements is in the form approved by our Board of Directors. Those indemnification agreements require that, under the circumstances and to the extent provided for therein, we indemnify such



persons to the fullest extent permitted by applicable law against certain expenses and other amounts incurred by any such person as a result of such person being made a party to certain actions, suits and proceedings by reason of the fact that such person is or was a director, officer, employee or agent of our company, any entity that was a predecessor corporation of our company or any of our affiliates. The rights of each person who is a party to such an indemnification agreement are in addition to any other rights such person may have under applicable Nevada law, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws, any other agreement, a vote of our stockholders, a resolution adopted by our Board of Directors or otherwise.

In July 2015, we issued and sold an aggregate of 10,302,736 shares of common stock at a price per share of \$2.75 pursuant to a registration statement on Form S-1, for an aggregate purchase price of approximately \$28.3 million. As part of the offering, OPI III and Associates III collectively purchased 500,000 shares of our common stock at the offering price of \$2.75 per share.

### Review, Approval or Ratification of Transactions with Related Persons

Pursuant to the written charter of our audit committee, the audit committee is responsible for reviewing and approving all transactions in which we are a participant and in which any parties related to us, including our executive officers, our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our Board of Directors determines may be considered related parties under Item 404 of Regulation S-K, has or will have a direct or indirect material interest. All of the transactions described in this section occurred prior to the adoption of the audit committee charter.

#### **Director Independence**

Our Board of Directors undertook a review of the composition of our Board of Directors and independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that each of Chau Khuong, Jean-Pierre Bizzari, Michael Richman, Julian Adams, Christopher Kiritsy and Steven Prelack would qualify as "independent" as that term is defined by NASDAQ Listing Rule 5605(a)(2). Stephen S. Yoder would not qualify as "independent" under applicable NASDAQ Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he currently serves as our Chief Executive Officer. In making such determinations, our Board of Directors considered the relationships that each of our non-employee directors has with our company and all other facts and circumstances deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Subject to some exceptions, NASDAQ Listing Rule 5605(a)(2) provides that a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, and that a director cannot be an "independent director" if (a) the director is, or in the past three years has been, an employee of ours; (b) a member of the director's immediate family is, or in the past three years has been, an executive officer of ours; (c) the director or a member of the director's immediate family has received more than \$120,000 per year in direct compensation from us within the preceding three years, other than for service as a director or benefits under a tax-qualified retirement plan or non-discretionary compensation (or, for a family member, as a non-executive employee); (d) the director or a member of the director or a member of the director's immediate family is, or in the past three years has been, employeed as an executive officer of a company where one of our executive officers serves on the compensation committee; or (f) the director or a member of the director's immediate family is an executive officer, partner or controlling stockholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or \$200,000 (except for

payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs). Additionally, in order to be considered an independent member of an audit committee under Rule 10A-3 of the Exchange Act, a member of an audit committee may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other committee of the Board of Directors, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the applicable company or any of its subsidiaries or otherwise be an affiliated person of the applicable company or any of its subsidiaries.

### Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Prior to April 4, 2016, the Audit Committee engaged Ernst & Young GmbH, or E&Y GmbH, as the Company's independent registered public accounting firm to act as the principal accountant to audit the Company's period ending 2015 financial statements. On April 4, 2016, the Audit Committee engaged Ernst & Young LLP, or E&Y LLP, as the Company's independent registered public accounting firm to act as the principal accountant to audit the Company's period ending 2016 financial statements.

The following table presents fees for professional audit services rendered by E&Y GmbH for the audit of the Company's annual financial statements for the year ended December 31, 2015 and fees billed for other services rendered by E&Y GmbH during those periods:

	2016	2015
Audit fees: (1)	\$74,563	\$396,873
Audit related fees: (2)		5,104
Tax fees:		
All other fees:		
Total	\$74,563	\$401,977

The following table presents fees for professional audit services rendered by E&Y LLP for the audit of the Company's annual financial statements for the year ended December 31, 2016 and fees billed for other services rendered by E&Y LLP during the period:

	2016	2015
Audit fees: (1)	\$646,061	
Audit related fees:	—	_
Tax fees:	—	
All other fees:		
Total	\$646,061	

- (1) Audit fees consisted of audit work performed on the annual financial statements, review of quarterly financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as the provision of consents in connection with the filing of registration statements, Current Reports on Form 8-K and related amendments and statutory audits.
- (2) Audit related fees consisted principally of fees relating to an audit for Pieris GmbH regarding the FP7 Grant Agreement, which is described in more detail under "Item 13. Certain Relationships and Related Transactions, and Director Independence."

### Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. Audit services include audit work performed on the annual financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. Audit-Related services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. Tax services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. Other Fees are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget at year end by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

#### PART IV

### Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Item 15(a). The following documents are filed as part of this annual report on Form 10-K:

Item 15(a)(1) and (2) See "Index to Consolidated Financial Statements" on page F-1 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Item 15(a)(3)

<u>Exhibits</u>

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description		Re	corporated by ference herein rom Form or Schedule	Filing Date	SEC File / Registration Number
2.1	Acquisition Agreement, dated as of December 17, 2014, by and among the Registrant, Pieris AG and the former stockholders of Pieris AG named therein		Form 8-	K (Exhibit 2.1)	December 18, 2014	333-190728
3.1	Amended and Restated Articles of Incorporation of the Registrant		Form 8-	K (Exhibit 3.1)	December 18, 2014	333-190728
3.2	Certificate of Designation of Series A Convertible Preferred Stock		Form 10	0-Q (Exhibit 3.1)	August 11, 2016	001-37471
3.3	Amended and Restated Bylaws of the Registrant		Form 8-	K (Exhibit 3.2)	December 18, 2014	333-190728
4.1	Form of Common Stock certificate		Form 8-	K (Exhibit 4.1)	December 18, 2014	333-190728
4.2	Form of Common Stock certificate		Form 10	-K (Exhibit 4.2)	March 23, 2016	001-37471
10.1	2014 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-	K (Exhibit 10.1)	December 18, 2014	333-190728
10.2	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-	K (Exhibit 10.2)	December 18, 2014	333-190728
10.3	2016 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-	K (Exhibit 10.1)	July 1, 2016	001-37471
10.4	Form of Stock Option Award Agreement under the Registrant's 2016 Employee, Director and Consultant Equity Incentive Plan	*				
10.5	Collaboration Agreement by and between Pieris AG and Allergan Sales, LLC, dated as of August 21, 2009	±	Form 8-	K (Exhibit 10.3)	December 18, 2014	333-190728
10.6	Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of September 24, 2010	±	Form 10	0-K (Exhibit 10.4)	March 30, 2014	333-190728

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.7	First Letter Agreement to Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of February 20, 2013	±	Form 8-K (Exhibit 10.5)	December 18, 2014	333-190728
10.8	Side Agreement to the Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur Inc., dated as of January 19, 2015	±	Form S-1 (Exhibit 10.6)	February 2, 2015	333-202123
10.9	Collaboration Research and Technology Licensing Agreement by and between Pieris AG and Daiichi Sankyo Company Limited, dated as of May 31, 2011	±	Form 10-K (Exhibit 10.7)	March 30, 2014	333-190728
10.10	Research and Licensing Agreement by and between Pieris AG and Technische Universität München, dated as of July 26, 2007	±	Form 10-K (Exhibit 10.10)	March 30, 2014	333-190728
10.11	Research Collaboration and License Agreement by and among the Registrant, Pieris GmbH, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd., dated as of December 8, 2015	±	Form 10-K/A		
10.12	License and Transfer Agreement by and between the Company and Enumeral Biomedical Holdings, Inc dated as of April 18, 2016	±	Form 10-Q/A (Exhibit 10.1)	July 20, 2016	001-37471
10.13	Definitive License and Transfer Agreement by and between the Company and Enumeral Biomedical Holdings, Inc. dated as of June 6, 2016	±	Form 10-Q (Exhibit 10.1)	August 11, 2016	001-37471
10.14	Amendment No.1 to Definitive License and Transfer Agreement by and between the Company and Enumeral Biomedical Holdings, Inc. effective as of January 3, 2017	*			
10.15	Collaboration Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017	*@			
10.16	Non-Exclusive Anticalin Platform Technology License Agreement Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017	*@			
10.17	Form of Indemnification Agreement by and between the Registrant and each of its current directors and executive officers	#	Form 8-K (Exhibit 10.10)	December 18, 2014	333-190728
10.18	Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of August 30, 2009	#	Form 8-K (Exhibit 10.11)	December 18, 2014	333-190728

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.19	Amendment to Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of March 12, 2012	#	Form 8-K (Exhibit 10.12)	December 18, 2014	333-190728
10.20	Amended and Restated Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 17, 2014		Form 8-K (Exhibit 10.13)	December 18, 2014	333-190728
10.21	Acknowledgement and Waiver Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 12, 2014		Form 8-K (Exhibit 10.14)	December 18, 2014	333-190728
10.22	Employment Agreement by and between the Registrant and Stephen S. Yoder, dated as of December 17, 2014	#	Form 8-K (Exhibit 10.15)	December 18, 2014	333-190728
10.23	Management Agreement by and between Pieris AG and Claus Schalper, dated as of February 6, 2008	#	Form 8-K (Exhibit 10.16)	December 18, 2014	333-190728
10.24	Consulting Agreement by and between Pieris AG and Claus Schalper, dated as of July 9, 2013	#	Form 8-K (Exhibit 10.17)	December 18, 2014	333-190728
10.25	Employment Agreement by and between the Registrant and Darlene Deptula-Hicks, dated as of August 27, 2015	#	Form 10-Q (Exhibit 10.2)	November 11, 2015	001-37471
10.26	Separation Agreement by and between the Registrant and Darlene Deptula-Hicks, dated as of February 7, 2017	*#			
10.27	Employment Agreement by and between the Registrant and Louis A. Matis, M.D., dated as of July 20, 2015	#	Form 10-Q (Exhibit 10.1)	November 11, 2015	001-37471
10.28	Employment Agreement by and between the Registrant and Claude Knopf, dated of November 14, 2016	*#			
10.29	Consulting Agreement by and between the Registrant and Danforth Advisors, LLC, dated as of February 1, 2017	*#			
10.30	Non-Employee Director Compensation Plan, as amended	*#			
10.31	Lease Agreement by and between Pieris AG and Födergesellschft IZB mbH, dated as of May 4, 2011		Form 8-K (Exhibit 10.23)	December 18, 2014	333-190728
10.32	Agreement of Sublease by and between Berenberg Capital Markets LLC and the Registrant, dated as of August 27, 2015		Form 10-Q (Exhibit 10.3)	November 11, 2015	001-37471
10.33	Repayment Agreement by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of April 3, 2014		Form 8-K (Exhibit 10.27)	December 18, 2014	333-190728

Exhibit Number	Exhibit Description	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.34	Settlement Agreement (Accelerated Repayment Agreement) by and between Pieris AG and tbg Technologie-Beteiligungs- Gesellschaft mbH, dated as of December 11, 2014	Form 8-K (Exhibit 10.28)	ę	333-190728
10.35	Consolidated Shareholders' Agreement 2014, Pieris AG, Freising, Germany, by and among Pieris AG and the Stockholders party thereto, dated October 10, 2014	Form 8-K (Exhibit 10.30)	December 18, 2014	333-190728
10.36	Investment Agreement, Pieris AG, Freising, Germany, by and among Pieris AG, Stephen Yoder and the Existing Shareholders party thereto, dated October 10, 2014	Form 8-K (Exhibit 10.31)	December 18, 2014	333-190728
10.37	Agreement, by and among Pieris AG and the Stockholders party thereto, dated December 5, 2014	Form 8-K (Exhibit 10.32)	December 18, 2014	333-190728
10.38	Form of Securities Purchase Agreement, dated December 17, 2014, by and among the Registrant and the Purchasers	Form 8-K (Exhibit 10.1)	December 23, 2014	333-190728
10.39	Form of Registration Rights Agreement, dated December 17, 2014, by and among the Registrant and the investors party thereto	Form 8-K (Exhibit 10.2)	December 23, 2014	333-190728
10.40	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by the Registrant	Form 8-K (Exhibit 10.3)	December 23, 2014	333-190728
10.41	Securities Purchase Agreement, dated June 2, 2016, by and among the Registrant and the Investors named therein	Form 8-K (Exhibit 10.1)	June 6, 2016	001-37471
10.42	Form of Warrant to purchase Common Stock, dated June 2, 2016, issued by the Registrant	Form 8-K (Exhibit 10.2)	June 6, 2016	001-37471
10.43	Registration Rights Agreement, dated June 2, 2016, by and among the Registrant and the Investors named therein	Form 8-K (Exhibit 10.3)	June 6, 2016	001-37471
14.1	Corporate Code of Ethics and Conduct and Whistleblower Policy	Form 10-K (Exhibit 14.1)	March 30, 2014	333-190728
21.1	List of Subsidiaries	*		
23.1	Consent of Ernst & Young LLP	*		
23.2	Consent of Ernst & Young GmbH Wirtschaftspüfungsgellschaft	*		
31.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	*		

31.2 Certification of Lance Thibault, Acting Chief Financial Officer, \* pursuant to Section 302 of the Sarbanes—Oxley Act of 2002

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
32.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350	**			
32.2	Certification of Lance Thibault, Acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350	**			
101.INS	XBRL Instance Document	*			
101.SCH	XBRL Taxonomy Extension Schema Document	*			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	*			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	*			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	*			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	*			

\* Filed herewith

\*\* Furnished herewith

± Confidential treatment received as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.

@ Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC

# Indicates a management contract or compensatory plan

### Item 16. 10-K SUMMARY

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

#### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### PIERIS PHARMACEUTICALS, INC.

Date: March 29, 2017

By: /s/ Stephen S. Yoder Stephen S. Yoder Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signature	Title	Date
/s/ Stephen S. Yoder Stephen S. Yoder	President, Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2017
/s/ Lance Thibault Lance Thibault	Acting Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 29, 2017
/s/ Chau Khuong Chau Khuong	Chairman of the Board of Directors	March 29, 2017
/s/ Jean-Pierre Bizzari Jean-Pierre Bizzari	Director	March 29, 2017
/s/ Michael Richman Michael Richman	Director	March 29, 2017
/s/ Steven Prelack Steven Prelack	Director	March 29, 2017
/s/ Julian Adams Julian Adams	Director	March 29, 2017
/s/ Christopher Kiritsy Christopher Kiritsy	Director	March 29, 2017

### PIERIS PHARMACEUTICALS, INC.

### **Table of Contents**

Report of Independent Registered Public Accounting Firm	F-
Report of Independent Registered Public Accounting Firm	2 F-
Consolidated Balance Sheets as of December 31, 2016 and 2015	F-
Consolidated Statements of Operations for the years ended December 31, 2016 and 2015	4 F-
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2016 and 2015	5 F-
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2016 and 2015	6 F-
Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015	7 F-
Notes to Consolidated Financial Statements	8 F-
	9

#### Report of Independent Registered Public Accounting Firm

#### The Board of Directors and Stockholders of Pieris Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Pieris Pharmaceuticals as of December 31, 2015, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for the year 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 audit.

We conducted our audit 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pieris Pharmaceuticals, Inc. at December 31, 2015, and the consolidated results of its operations and its cash flows for the year ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Dr. Napolitano Wirtschaftsprüfer [German Public Auditor] /s/ Christ Wirtschaftsprüfer [German Public Auditor]

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Munich, Germany March 23, 2016

### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Pieris Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Pieris Pharmaceuticals, Inc. (the "Company") as of December 31, 2016, and the related consolidated statements of operations, comprehensive loss, stockholder's equity, and cash flows for the year then ended. 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 audit.

We conducted our audit 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pieris Pharmaceuticals, Inc. at December 31, 2016 and the consolidated results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts March 29, 2017

# PIERIS PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

	December 31,		
	2016	2015	
Assets			
Current assets:			
Cash	\$ 29,355,528	\$ 29,349,124	
Accounts receivable	57,582		
Prepaid expenses and other current assets	3,259,503	2,311,385	
Total current assets	32,672,613	31,660,509	
Property and equipment, net	2,264,477	2,162,771	
Other non-current assets	125,741	126,781	
Total assets	\$ 35,062,831	\$ 33,950,061	
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$ 2,386,183	\$ 1,058,536	
Accrued expenses and other current liabilities	3,719,457	1,739,380	
Deferred revenues, current portion	2,274,514		
Total current liabilities	8,380,154	2,797,916	
Deferred revenue, net of current portion	1,409,483	—	
Other long-term liabilities	46,667	23,852	
Total liabilities	9,836,304	2,821,768	
Stockholders' equity:			
Preferred stock, \$0.001 par value per share, 4,963 shares authorized and 4,963 and zero issued and outstanding at December 31, 2016 and December 31, 2015	5	_	
Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 43,058,827			
and 39,833,023 issued and outstanding at December 31, 2016 and December 31, 2015	43,059	39,833	
Additional paid-in capital	129,349,768	112,226,723	
Accumulated other comprehensive loss	(1,501,452)	(1,272,574)	
Accumulated deficit	(102,664,853)	(79,865,689)	
Total stockholders' equity	25,226,527	31,128,293	
Total liabilities and stockholders' equity	\$ 35,062,831	\$ 33,950,061	

The accompanying notes are an integral part of these consolidated financial statements.

# PIERIS PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended l	Years ended December 31,		
	2016	2015		
Revenue	\$ 5,830,674	\$ 2,931,931		
Operating expenses				
Research and development	19,698,803	8,244,751		
General and administrative	8,890,886	8,368,215		
Total operating expenses	28,589,689	16,612,966		
Loss from operations	(22,759,015)	(13,681,035)		
Interest income (expense), net	2,320	(184,645)		
Other income, net	119,501	10,905		
Loss before income taxes	(22,637,194)	(13,854,775)		
Provision for income tax	161,970	203,866		
Net Loss	<u>\$(22,799,164)</u>	\$(14,058,641)		
Net loss per share				
Basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.41)</u>		
Weighted average number of common shares outstanding				
Basic and diluted	41,713,223	34,392,636		

The accompanying notes are an integral part of these consolidated financial statements.

# PIERIS PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years ended I	Years ended December 31,		
	2016	2015		
Net loss	\$22,799,164	\$14,058,641		
Other comprehensive income/(loss) components:				
Foreign currency translation	(228,878)	(429,477)		
Total other comprehensive income/(loss)	(228,878)	(429,477)		
Comprehensive loss	\$23,028,042	\$14,488,118		

The accompanying notes are an integral part of these consolidated financial statements.

### PIERIS PHARMACEUTICALS, INC.

# CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Convertible Series A Preferred shares Common shares		Accumulated Additional other					
	No. of	Share	No. of	Share	paid-in	comprehensive	Accumulated	
	shares	capital	shares	capital	capital	loss	deficit	Total equity
Balance as of January 1, 2015			29,279,522	29,280	84,627,283	(843,097)	(65,807,048)	18,006,418
Net loss	—	—		_		_	(14,058,641)	(14,058,641)
Foreign currency translation adjustment	_	_		_		(429,477)		(429,477)
Stock based compensation expense	—	—		_	1,164,633	—	_	1,164,633
Issuance of restricted shares	—	—	150,000	150	446,250	—	—	446,400
Issuance of consulting shares	—	—	95,765	95	224,905	—		225,000
Issuance of Common Stock net \$2,568,565 in offering								
costs	—	—	10,302,736	10,303	25,753,657	—	—	25,763,960
Options exercised			5,000	5	9,995			10,000
Balance as of December 31, 2015		_	39,833,023	39,833	112,226,722	(1,272,574)	(79,865,689)	31,128,293
Net loss	—	—		_		—	(22,799,164)	(22,799,164)
Foreign currency translation adjustment	—	—	—	—	—	(228,878)	—	(228,878)
Stock based compensation expense			—	—	1,905,256		—	1,905,256
Issuance of Common and Preferred stock, net								
\$1,279,419 in offering costs	4,963	5	3,225,804	3,226	15,217,790			15,221,021
Balance as of December 31, 2016	4,963	5	43,058,827	43,059	129,349,768	(1,501,452)	(102,664,853)	25,226,527

The accompanying notes are an integral part of these consolidated financial statements.

## PIERIS PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2016	2015	
Operating activities:			
Net loss	\$(22,799,164)	\$(14,058,641)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	361,382	307,906	
Stock-based compensation	1,905,256	1,164,633	
Disposal of fixed assets	49,437	_	
Non-cash restricted shares		446,400	
Non-cash consulting shares		225,000	
Changes in operating assets and liabilities:			
Accounts receivable	(58,651)	—	
Prepaid expenses and other assets	(1,019,665)	(1,256,151)	
Deferred Revenue	3,752,400	—	
Accounts payable	1,360,274	(90,924)	
Accrued expenses and other current liabilities	2,060,797	556,297	
Net cash used in operating activities	(14,387,934)	(12,705,480	
Investing activities:			
Purchase of property and equipment	(580,639)	(620,747	
Proceeds from sale of property and equipment	20,968	_	
Net cash used in investing activities	(559,671)	(620,747	
Financing activities:			
Proceeds from exercise of options	_	10,000	
Issuance of Common and Preferred Stock, net of issuance costs	15,221,021	25,763,960	
Repayment of debt		(1,157,940	
Net cash used in financing activities	15,221,021	24,616,020	
Effect of exchange rate change on cash and cash equivalents	(267,012)	(414,880)	
Net increase in cash and cash equivalents	6,404	10,874,913	
Cash and cash equivalents at beginning of year	29,349,124	18,474,211	
Cash and cash equivalents at end of year	\$ 29,355,528	\$ 29,349,124	
Supplemental cash flow disclosures:			
Cash paid for interest	\$ —	\$ 206,269	
Cash paid for income taxes	\$ 161,970	\$ 203,866	
Property and equipment included in accounts payable	\$ 21,706	\$ —	

The accompanying notes are an integral part of these consolidated financial statements.

### PIERIS PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Corporate Information

Pieris Pharmaceuticals, Inc. was founded in May 2013 and is a holding company. On December 17, 2014 Pieris Pharmaceuticals GmbH ("Pieris GmbH") (formerly Pieris AG, a German company which was founded in 2001 by Prof. Dr. Arne Skerra, Professor at the Technical University of Munich, Germany, and Claus Schalper) became a wholly owned subsidiary of Pieris Pharmaceuticals, Inc., which was previously named Marika Inc. pursuant to a share exchange transaction (the "Acquisition"). The registered office of Pieris Pharmaceuticals, Inc. and the corporate headquarters is located in Boston, MA and the research facility of Pieris GmbH is located in Freising-Weihenstephan, Germany. Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris GmbH, was formed on February 14, 2014 to conduct research and development in Australia.

Effective as of August 26, 2015 and with notification from the Amtsgericht München as of September 29, 2015, Pieris AG was transformed to Pieris GmbH as a result of a change in the legal entity. Pieris Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively "Pieris" or the "Company") is a clinical-stage biopharmaceutical company that discovers and develops Anticalin based drugs to target validated disease pathways in a unique and transformative way.

The Company's pipeline includes, among other programs, an immuno-oncology multispecific tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma, and a half-life-optimized Anticalin to treat anemia.

The Company's core Anticalin technology and platform was developed in Germany, and the Company has partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe, Japan, and with regional pharmaceutical companies headquartered in India.

### 2. Summary of Significant Accounting Policies

#### **Basis of Consolidation**

The accompanying consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly owned subsidiaries were prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

### Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition, deferred tax assets, liabilities and valuation allowances, fair value of stock options and various accruals. Management evaluates its estimates on an ongoing basis. Actual results and outcomes could differ materially from management's estimates, judgments, and assumptions.

#### **Foreign Currency Translation**

The financial statements of Pieris' foreign subsidiaries are translated from local currency into reporting currency, which is U.S. dollars, using the current exchange rate at the balance sheet date for assets and liabilities, and the average exchange rate prevailing during the period for revenues and expenses. The functional currency for Pieris'



foreign subsidiaries is considered to be the local currency for each entity and, accordingly, translation adjustments for these subsidiaries are included in accumulated other comprehensive loss within stockholders' equity.

Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as other income (expense), net in the consolidated statements of operations.

#### Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents consist of cash on deposit in banks and other cash invested temporarily in money-market funds that are highly liquid and have an original maturity of less than 90 days at the date of purchase.

The Company held no restricted cash as of December 31, 2016. As of December 31, 2015 the Company held \$17,302 in restricted cash. Such bank balances in 2015 related to prepayments received by the Company pursuant to EU grants under the EUROCALIN program (see Note 3 *Revenue*). These 2015 amounts, recorded to other current assets, were restricted to cover future obligations to members of the EUROCALIN consortium; they were not available for use by the Company. During 2016, at the conclusion of the EUROCALIN program, the Company made all distributions of cash related to the EU grant program.

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements through the filing of our 2017 financial statements.

### Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents and accounts receivable. Pieris maintains cash with various major financial institutions. Pieris had no cash equivalents as of December 31, 2016 and 2015. Pieris maintains deposits and owns money market funds only in highly rated financial institutions to minimize the credit risk from the financial institutions. There were no money market funds held at December 31, 2016. Management periodically reviews the credit standing of these financial institutions and believes that Pieris is not exposed to significant credit risk from the institutions in which those deposits are held.

As of December 31, 2016 and December 31, 2015, Pieris is not exposed to significant credit risks from accounts receivable. Pieris relies on third parties to conduct preclinical and clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Pieris may not be able to obtain regulatory approval for Pieris's drug candidates and Pieris's business could be substantially impacted. Furthermore, Pieris is exposed to the risks associated with third parties formulating and manufacturing its preclinical and clinical drug supplies and any approved product candidates. The development and commercialization of any of its drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide Pieris with sufficient quantities of such drug candidate or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements and prices.

In line with such third-party risk, Pieris depends significantly on the Research and Licensing Agreement (or the "TUM License Agreement") with Technische Universität München ("TUM" or "Technical University Munich"), under which certain intellectual property rights are exclusively licensed to Pieris. In the event that the TUM License Agreement is terminated by TUM, Pieris would be significantly hampered in its efforts to develop and commercialize, as well as to sub-license, the drug candidates covered by such exclusive license.

#### Accounts Receivable

Accounts receivable are recorded net of allowances for doubtful accounts and represent amounts due from third parties and collaboration partners. Management monitors and evaluates collectability of receivables on an ongoing basis and considers whether an allowance for doubtful accounts is necessary. Management determined that no such reserve is needed as of December 31, 2016 and 2015. Historically, Pieris has not had collectability issues with third parties and collaboration partners.



### **Property and Equipment**

Property and equipment are recorded at acquisition cost, less accumulated depreciation and impairment. Depreciation on property and equipment is calculated using the straight-line method over the remaining estimated useful lives of the assets. Maintenance and repairs to these assets are charged to expenses as occurred. The estimated useful life of the different groups of property and equipment is as follows:

Asset Classification	Estimated useful life (in years)
Leasehold improvements	shorter of useful life or remaining life of the lease
Laboratory equipment	1 - 14
Office and computer equipment	1 - 15

#### **Impairment of Long-lived Assets**

Pieris reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Pieris evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets. Pieris believes that, as of each of the balance sheets presented, none of Pieris' long-lived assets were impaired.

#### **Revenue Recognition**

Pieris has entered into several licensing and development agreements with collaboration partners for the development of Anticalin<sup>®</sup> therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include: (i) licenses, or options to obtain licenses, to Pieris's Anticalin technology and (ii) research activities to be performed on behalf of the collaborative partner. Payments to Pieris under these agreements may include upfront fees (which include license and option fees), payments for research activities, payments based upon the achievement of certain milestones and royalties on product sales. There are no performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris. Pieris follows the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

#### Multiple-Element Arrangements

When evaluating multiple-element arrangements, Pieris identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the customer or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. Pieris has used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because Pieris does not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, Pieris considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating Pieris' best estimate of selling price, Pieris evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with generally accepted accounting principles, or U.S. GAAP. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value. If the license is considered to not have stand-alone value, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

If the Company is involved in a steering committee as part of a multiple element arrangement, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The Company recognizes revenue using the relative performance method provided that the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Full-time equivalents are typically used as the measure of performance.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

The accounting treatment for options granted to collaborators is dependent upon the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of an agreement, Pieris is at risk as to whether the collaborative partner will choose to exercise the options to secure additional goods or services. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

In arrangements where options to obtain additional deliverables are considered substantive, Pieris determines whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and incremental discount, the option is considered a deliverable in the arrangement. However, if not priced at a discount, the elements included in the arrangement are considered to be only the non-contingent elements. When a collaborator exercises an option to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and Pieris applies the multiple-element revenue recognition criteria to determine accounting treatment. All of Pieris' agreements with options have been determined to include substantive options.

Payments or reimbursements resulting from Pieris' research and development efforts in multi-element arrangements in which Pieris's research and development efforts are considered deliverable are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

#### Milestone Payments and Royalties

At the inception of each agreement that includes milestone payments, Pieris evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. Pieris evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment.

Pieris aggregates milestones into four categories: (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Sales milestones are typically achieved when an approved pharmaceutical product exceed net sales as defined in each agreement.

For revenues from research, development and sales milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the period of performance. To date, Pieris has determined all milestones are substantive. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

#### Government Grants

Government grants are recognized when there is reasonable assurance that all conditions will be complied with and the grant will be received. As the government grants generally represent subsidies for specified activities, they are recognized when earned as revenue from grants. Otherwise, government grants are credited against the expenses incurred to receive the grant.

Funds received that are not related to research and development expenses that have already been incurred, such as the EUROCALIN grant, are recorded as deferred revenue until such time that the related expenses have been incurred by Pieris or by one of the other members of the EUROCALIN consortium. At the time eligible expenses are incurred, the applicable portion of deferred revenue, according to the respective funding rates, is recorded as revenue from grants.

### **Research and Development**

Research and development expenses are charged to the statement of operations as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, pre-clinical and clinical costs, contract services, consulting, depreciation and amortization expense, and other related costs. Costs associated with acquired technology, in the form of upfront fees or milestone payments, are charged to research and development expense as incurred.

#### **Income Taxes**

The Company applies ASC 740—*Income Taxes*, which established financial accounting and reporting requirements for the effects of income taxes that result from the Company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Where the Company determines that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance. The Company records interest related and penalties related to uncertain tax positions as part of income tax expense.

From time to time, the Company may receive tax credits in the form of cash in our Australian jurisdiction, irrespective of a tax liability. The Australian R&D Tax Incentive credit is a self-assessed, entitlement program that provides a credit for eligible R&D entities engaging in R&D activities. The level of credit for years starting before 1 July 2016 is a 45% refundable credit where the R&D entity's aggregated turnover for the income tax year is less than \$20 million and at any time during the income tax year the R&D entity is not controlled by an exempt entity or combination of exempt entities per s 328-125 of the Income Tax Assessment Act 1997 (ITAA 97). The entity submitted an Advance and Overseas Finding application, which was approved and awarded certificates OF00630 for the year beginning 1 January 2015. The Advance and Overseas finding certification is in force for the following two income years for Australian activities and until completion for overseas activities. This application detailed the R&D activities to be conducted in Australia and overseas. The Company records the Australian R&D tax credit as an offset to research and development expenses in the consolidated statements of operations, as this was where the original expense was recorded. For the years ended December 31, 2016 and 2015 the Company recorded \$1.5 million and \$0.4 million, respectively. As of December 31, 2016, the Company recorded a receivable for \$1.5 million related to the Australian R&D Tax Incentive credit.

#### **Stock-based Compensation**

Pieris measures share-based payments in accordance with ASC Topic 718, *Stock Compensation*. Pieris records its stock-based compensation expense over the requisite service period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. For employee options, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite period of the awards, less expense for actual forfeitures.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility, risk free interest rate and forfeitures of the underlying stock. Accordingly, the weighted-average fair value of the options granted during the years ended December 31, 2016 and 2015 was \$1.00 and \$1.87, respectively based on the following assumptions:

	Years Ended December 31,		
	2016 2015		
Risk free interest rate	1.13%-2.08%	1.47%-1.89%	
Expected term	5.0 – 5.7 years	5.0 - 6.1 years	
Dividend yield	—	_	
Expected volatility	74.90%-76.00%	72.65%-75.07%	

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities, and other factors due to the lack of historic information of the Company's common stock. The expected life of stock-based options is the period of time for which the stock-based options are expected to be outstanding. Given the lack of historic exercise data, the expected life is determined using the "simplified method" which is defined as the midpoint between the vesting date and the end of the contractual term. Under the new guidance of ASU No. 2016-09, "*Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*", the Company is required to elect whether to account for forfeitures of share-based payments by (i) recognizing forfeitures of awards as they occur, or (ii) estimating the number of awards expected to be forfeited and adjusting the estimate when it is no longer probable that the employee will fulfill the service condition, as is currently required. The Company has decided to early adopt this ASU from the beginning of the 2016 period and the Company's accounting policy is to account for forfeitures when they occur. Refer to Note 9 *Stock-Based Compensation*, for further information.

Pieris recorded stock-based compensation expense of \$1.9 million and \$1.2 million for the years ended December 31, 2016 and 2015, respectively.

Total stock-based compensation expense was recorded in operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows:

		Years Ended December 31,		
	2016	2015		
Research and development	\$ 599,138	\$ 379,066		
General and administrative	1,306,118	785,567		
Total stock-based compensation	\$1,905,256	\$1,164,633		

#### Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. Pieris evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, Pieris determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, Pieris carries out an evaluation of disclosure requirements and considers possible accruals in the financial statements.

#### Segment Reporting

Operating segments are identified as components of an enterprise where separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources

and assess performance. Pieris operates as a single segment dedicated to the discovery and development of biotechnological applications and the Company's chief operating decision maker ("CODM") makes decisions based on the Company as a whole. The Company has determined that its CODM is its Chief Executive Officer.

#### Net Loss per Common Share

Basic net loss per share was determined by dividing net loss by the weighted average common shares outstanding during the period. Diluted net loss per share was determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflect the dilutive effect, if any, of common stock options based on the treasury stock method.

For all financial statement periods presented the number of basic and diluted weighted average shares outstanding was the same because any increase in the number of shares of common stock equivalents for any period presented would be antidilutive based on the net loss for the period.

Shares to be issued upon the exercise of the outstanding options and warrants excluded from the loss per share calculation amounted to \$ 8.2 million and 2.6 million for the year ended December 31, 2016 and 2015 respectively, because the awards were anti-dilutive.

### **Recent Accounting Pronouncements**

#### Adopted Standards for current period

In August 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its financial obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization's management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. As of December 31, 2016, the Company has adopted this ASU and the Company is not required to make any additional disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting". ASU 2016-09 simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including accounting for income taxes, classification of excess tax benefits on the statement of cash flows, forfeitures, statutory tax withholding requirements, classification of awards as either equity or liabilities and classification of employee taxes paid on the statement of cash flows when an employer withholds shares for tax-withholding purposes. ASU No. 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company has decided to early adopt ASU 2016-09 from the beginning of the 2016 period to simplify the accounting for share-based payments. As a result of the early adoption of ASU 2016-09, the Company decided to account for forfeitures when they occur. In the 2015 period, the Company estimated forfeitures to determine stock-based compensation expense and recognized a cumulative-effect adjustment of \$0.1 million as of December 31, 2015. During the period of adoption in 2016, no other aspects of ASU 2016-09 had a material effect on the Company's consolidated financial statements or related footnote disclosure.

#### Standards not yet adopted

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). Subsequently, the FASB also issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), which adjusted the effective date of ASU 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies identifying performance obligation and licensing implementation guidance and illustrations in ASU 2014-09; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients , which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09 (collectively, the "Revenue ASUs").

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2017, with an option to early adopt for interim and annual periods beginning after December 15, 2016. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). We currently anticipate adoption of the new standard effective January 1, 2018 under the modified retrospective method. The Company is in the process of determining the impact of the Revenue Recognition ASUs on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*". Under the amendments in ASU 2016-02, lessees will be required to recognize (i) a lease liability, which is a lessees obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date. This guidance is effective for fiscal years beginning after December 15, 2019 including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

Pieris has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the unaudited condensed consolidated financial statements as a result of future adoption.

#### 3. Revenue

#### General

The Company has not generated revenue from product sales. The Company has generated revenue pursuant to (i) license and collaboration agreements, which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments, and (ii) government grants.

	Years ended	Years ended December 31,		
	2016	2015		
License fees	\$2,735,794	\$		
Research and development services	1,439,513	5,593		
Milestone payments	1,655,367	2,538,698		
Government grants		369,200		
Other Revenues		18,440		
Total Revenue	\$5,830,674	\$2,931,931		

Revenue from two collaboration partners exceeded 10% of total revenue, amounting to \$1.7 million and \$4.1 million, respectively, in the year ended December 31, 2016. Revenue from two collaboration partners and from one government grant exceeded 10% of total revenue, amounting to \$2.0 million, \$0.5 million and \$0.4 million, respectively, in the year ended December 31, 2015.

#### **Collaborations and Other Agreements**

### Daiichi Sankyo Co., Ltd.

In May 2011, Pieris granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company for targets selected by Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") pursuant to an agreement with Daiichi Sankyo. Under this agreement, Pieris will use its proprietary Anticalin scaffold technology to identify drug candidates against certain selected targets, with further development and commercialization performed by Daiichi Sankyo.

Daiichi Sankyo has agreed to pay various upfront payments for certain research programs, payments for services provided by Pieris in conjunction with the research programs, and certain milestone payments as development milestones are achieved. During the years ended December 31, 2016 and 2015, Pieris recorded revenue of \$1.7 million and \$2.0 million, respectively. The revenues recorded during the year ended December 31, 2016 were associated with achieving a milestone within a research program and to a lesser extent Pieris providing various services in connection with a research program. The revenues recorded during the year ended December 31, 2015 were associated with achieving certain milestones within a research program.

The milestone payments in 2016 and 2015 are based on successful in vitro and in vivo studies and for the initiation on a toxicity study in non-human primates. The milestones could not be achieved solely upon the passage of time. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. Therefore, each of the milestone payments were recognized net of Japanese withholding tax of 10%, as revenues during the respective years ended December 31, 2016 and 2015 in which they were received.

Pieris is able to receive potential milestone payments of \$85.9 million, plus royalties on the commercial sales of any commercial products. The total milestones are categorized as follows: research milestones—\$2.5 million; development milestones—\$35.2 million; commercial milestones—\$47.3 million; additional diagnostic milestones of \$0.7 million.

#### Sanofi-Aventis and Sanofi-Pasteur

In September 2010, the Company entered into an agreement with Sanofi-Aventis and Sanofi Pasteur ("Sanofi"), under which the Company agreed to apply its proprietary Anticalin technology to identify drug candidates against certain targets selected by Sanofi, with further development and commercialization performed by Sanofi. The agreement included the initial identification of two targets by Sanofi, with options to select up to four additional targets. For any targets selected by Sanofi, the Company granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company. In addition to the two initial targets selected by Sanofi, Sanofi exercised one of the four options and received a license. The remaining three options expired unexercised.

Sanofi has agreed to pay various upfront payments for certain research programs, payments for services provided by Pieris in conjunction with the research programs and certain milestone payments as development milestones are achieved. During the years ended December 31, 2016 and 2015, Pieris recorded revenue of zero and \$0.5 million, respectively. The revenues recorded during the year ended December 31, 2015 were associated with achieving a development milestone within a research program during the period.

No milestone payments were achieved during the year ended December 31, 2016. The milestone payment in 2015 resulted from Sanofi's decision to continue advancing the tetraspecific Anticalin-based program for infectious disease. The milestone could not be achieved solely upon the passage of time. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. Therefore, the milestone payment was recognized in its entirety as revenue during the respective year ended December 31, 2015 in which it was received.

The Company is able to receive milestone payments up to \$48.6 million, plus royalties on the sales of any commercial products. The total future potential milestones are categorized as follows: research milestones—\$1.8 million; development milestones—\$27.9 million; commercial milestones—\$18.9 million.

#### F.Hoffmann-La Roche Ltd and Hoffmann- La Roche Inc.

In December 2015, the Company entered into a Research Collaboration and License Agreement (the "Roche Agreement") with F.Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., ("Roche"), for the research, development, and commercialization of Anticalinbased drug candidates against a predefined, undisclosed target in cancer immune therapy. The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalin proteins that bind to a specific target for an expected period of 20 months, which may be extended by Roche for up to an additional 12 months. Roche has the ability to continue exclusivity rights for up to an additional 5 years. Both Roche and the Company will participate in a joint research committee in connection with this agreement. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product developed through the research plan and will have worldwide commercialization rights to any such product.

Roche has paid \$6.5 million of an upfront payment for the research collaboration. Additionally, Roche will pay Pieris for research services provided by Pieris in conjunction with the research program. Roche will also pay Pieris for certain milestones relating to development, regulatory, and sales milestones, as they are achieved. As of December 31, 2016 and December 31, 2015, deferred revenue, related to Roche collaboration, is \$3.7 million and \$0, respectively.

Pieris recorded \$4.1 million in revenue for the year ended December 31, 2016, related to the recognition of the upfront Roche payment and the research services provided during those periods. Revenue recognized is associated with the portion of the research services performed during the periods as well as the value of research services provided by Pieris in connection with the ongoing research program. No revenues were recorded for the year ended December 31, 2015.

The Company identified the research and commercial licenses, performance of R&D services, and participation in the joint research committee as deliverables under the Roche Agreement. For revenue recognition purposes, management has determined that there are two units of accounting at the inception of the agreement representing (i) the research and commercial licenses and the performance of R&D services which do not have standalone value, and (ii) the participation in the joint research committee.

In addition to the upfront payment, under the Roche Agreement, the Company is eligible to receive research funding, development and regulatory and sales based milestone payments up to approximately \$399.4 million, plus royalties on future sales of any commercial products. The total potential milestones are categorized as follows: development and regulatory milestones—\$277.6 million and sales milestones—\$117.7 million. Management has determined that the development milestones are not substantive because they do not relate solely to past performance of the Company and the Company's involvement in the achievement is limited to progress reports and other updates. Non-substantive milestones will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement.

### **Other Collaborations**

The Company has entered into several other research and collaboration agreements for which the Company could achieve future milestone payments up to \$14.0 million. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. No milestones or other revenues related to these agreements were recognized during the years ended December 31, 2016 and 2015, respectively.

### **Government Grants**

#### **BioCluster m4**

In 2011 Pieris applied for a government grant from the German Federal Ministry for Education and Research for the project "Spitzencluster m4, Cooperation personalized medicine: 'Preclinical development of PRS-110 an Anticalin targeted against c-Met as a monovalent antagonist in the field of oncology (PM18).'" The funding rate amounts to 40% of the actual costs incurred, with an aggregate cap of \$1.4 million for the approval period from February 1, 2012 to September 30, 2014. The amounts received are non-refundable, and the grant funds may only be claimed for costs incurred within the approval period.

The payments are received quarterly in arrears based on expenses already incurred. The Company recorded zero and \$8,654 for the years ended December 31, 2016 and 2015, respectively, which was recorded as grant revenue.

# Seventh Research Framework Program ("FP7")—Collaborative Project "EUROCALIN—European consortium for antiCALINs as next generation high-affinity protein therapeutics" ("EUROCALIN")

EUROCALIN is a program that started in August 2011 with the objective of developing and producing new high-affinity protein scaffolds for therapeutic use. The focus is on the development of non-immunoglobulin protein scaffolds as alternatives to antibodies and oligonucleotides. The grant involves a consortium of ten companies and universities in Europe and was initiated for a collaboration focused on attaining and completing initial clinical development of a novel Anticalin therapeutic. The consortium is seeking to develop, manufacture and clinically test an Anticalin specific for hepcidin. The program is a small molecule enhancers ("SME") targeted project, which is funded by the European Union ("EU") in the amount of \$7.3 million and also includes a respective funding rate of approximately 64% of the eligible costs occurred in connection with the research project. All payments received from the EU in connection with the grant are non-refundable. Under this grant agreement, Pieris is the coordinator. The EU has scheduled three tranches of payments. The first tranche (pre-financing) was received as of December 7, 2011 and the second tranche as of August 4, 2013. The third tranche was completed in November 2015. Pieris, as the coordinator, received all payments from the grant. During 2016, at the conclusion of the EUROCALIN program, the Company made all distributions of cash to the members of the consortium that are entitled to payments based on submission of invoices of eligible costs. Under this program, the Company recognized zero and \$0.4 million as revenue from grant during the years ended December 31, 2016 and 2015, respectively.

The following balance sheet items relate to the FP7 agreement:

	Years Ended December 31,		
	2016		2015
Other current assets (receivables from FP7 grant)	\$ -	\$	980,936
Cash (restricted cash)	\$ -		17,302
Accounts payable	\$ -		424,441

## 4. Fair Value Measurement

ASC Topic 820 *Fair Value Measurement* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. Pieris applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement.

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

For the periods presented in these consolidated financial statements, Pieris has no cash equivalents, investments or debt instruments as of each balance sheet date presented.

All other current assets and current liabilities on our consolidated balance sheets approximate their respective carrying amounts.

### 5. Property and Equipment, net

Property and equipment are summarized as follows:

	Years Ended December 31,		
	2016	2015	
Laboratory equipment	\$ 3,869,154	\$ 3,701,517	
Office and computer equipment	499,233	443,562	
Leasehold improvements	320,750	304,363	
Property and equipment at cost	4,689,137	4,449,442	
Accumulated depreciation	(2,424,660)	(2,286,671)	
Property and equipment, net	\$ 2,264,477	\$ 2,162,771	

Depreciation expense was \$0.4 million and \$0.3 million for the years ended December 31, 2016 and 2015, respectively. There were no other changes in accumulated depreciation other than foreign currency impact. 86% of the Company's property and equipment are located in Germany and the remaining 14% are located in the United States.

### 6. Income Taxes

(Loss) before income taxes consists of the following:

	Years Ended I	Years Ended December 31,		
	2016	2015		
Domestic	\$ (8,724,628)	\$ (7,563,300)		
Foreign	(13,912,568)	(6,291,475)		
Loss before income taxes	<u>\$(22,637,196)</u>	<u>\$(13,854,775)</u>		



The components of the provision (benefit) for income taxes are as follows:

	Years Ended	Years Ended December 31,		
	2016	2015		
Current:				
Federal	\$ —	\$ —		
State		_		
Foreign	161,970	203,866		
Total current	161,970	203,866		
Deferred:				
Federal	—	—		
State	—	—		
Foreign				
Total deferred				
Provision (benefit) for income taxes	\$ 161,970	\$ 203,866		

The reconciliation of the federal statutory rate to Pieris' effective tax rate is as follows:

	2016	2015
Federal income tax rate	34.0%	34.0%
Foreign rate differential	(2.9)	(2.1)
State tax, net of federal benefit	0.9	3.1
Permanent items	(2.3)	(1.7)
Other	(0.9)	2.9
Withholding tax	(0.7)	(1.5)
Change in valuation allowance	(28.8)	(36.2)
Effective income tax rate	(0.7)%	(1.5)%

The components of deferred tax assets and liabilities related to net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income taxes purposes were as follows:

	Years Ended	Years Ended December 31,		
	2016	2015		
Deferred tax assets:				
Net operating loss carryforwards	\$ 18,498,365	\$ 13,052,809		
Share based awards compensation	1,080,314	692,906		
Accrued compensation/other	190,799	139,773		
Accrued expenses	35,888	4,201		
Depreciation	12,065	12,276		
Total deferred tax assets	19,817,431	13,901,965		
Less: valuation allowance:	(19,817,431)	(13,901,965)		
Net deferred tax asset	\$ —	\$		

The Company operates in multiple countries. Accordingly, the Company files federal income tax returns as well as returns in multiple foreign jurisdictions. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations will not generate sufficient taxable income in the U.S. or in its foreign jurisdictions to realize the full benefits of its deferred tax assets. As of December 31, 2016, we continue to maintain a full valuation allowance against all net deferred tax assets.

The increase in the valuation allowance of deferred tax assets of \$5.9 million was primarily influenced by the operating losses generated in current tax year. The overall increase is offset to a lesser extent the impact of foreign currency translation.

As of December 31, 2016, the Company had net operating loss carryforwards for United States federal income tax purposes of \$12.9 million and net operating loss carryforwards for state income tax purposes of \$9.8 million. These tax loss carryforwards, originating subsequent to reverse merger, expire through 2036. In the United States, utilization of the NOL carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not currently completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since the Acquisition.

As of December 31, 2016, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately \$66.3 million and \$64.9 million respectively. Based on German tax law, the losses can be carried forward indefinitely. The operating loss carryforwards generated are subject to restrictions under German tax law. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership. The Company files federal income tax returns as well as returns in multiple foreign jurisdictions. Tax years ended December 31, 2013 or later remain subject to examination by the German tax authorities.

As of December 31, 2016, the Company had Australia tax net operating loss carryforwards of approximately \$0.3 million, originating subsequent to the reverse merger, can be carried forward indefinitely.

The Company revised the carrying value as of December 31, 2015 of its deferred tax asset for net operating loss carryforwards in foreign jurisdictions by \$8.9 million. The increase in the deferred tax asset was offset by a corresponding increase in the Company's valuation allowance. This adjustment is to accurately reflect the value of net operating losses that the Company believes it is entitled to benefit from to offset future income, if any, in foreign jurisdictions.

The Company accounts for uncertain tax positions pursuant to ASC 740 which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured at the largest amount of benefit that is more likely than not (determined by cumulative probability) of being realized upon ultimate settlement with the taxing authority. The Company recorded an uncertain tax position related to a prior year position, that if successfully challenged by tax authorities could result in the loss of certain tax attributes. The balance of uncertain tax positions will remain until such time that settlement is reached with the relevant tax authorities or should the statute of limitations expire. The Company recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. No interest and penalties related to uncertain tax positions were accrued at December 31, 2016 and December 31, 2015.

The following table sets forth a reconciliation of the beginning and ending amounts of unrecognized tax benefits, excluding the impact of interest and penalties, for the years ended December 31, 2016 and 2015:

Unrecognized tax benefits at December 31, 2015	\$ —
Increase for tax positions taken during the current period	5,654,803
Unrecognized tax benefits at December 31, 2016	\$5,654,803

The Company does not expect unrecognized tax benefits to change significantly over the next twelve months. The full amount of unrecognized tax benefits would impact the effective rate, subject to valuation allowance considerations, if recognized.

#### 7. Debt

#### **Unsecured Bank Loan**

In May 2003, the Company signed an unsecured loan agreement (the "Bank Loan") under a silent partnership agreement with Technologie-Beteiligungs-Gesellschaft ("TBG"), a minority interest stockholder. As of April 3, 2014, the Company and TBG, the subsidiary of KfW Bank, Frankfurt ("KfW"), signed a repayment agreement concerning the Company's repayment of its liabilities to TBG outstanding at December 31, 2013 in a total amount of  $\notin 1.2$  million (\$1.34 million). The principal amount bore interest at a rate of 10.53%. On December 11, 2014, the Company and TBG entered into an accelerated repayment agreement in respect of the claims of TBG against the Company. Pursuant to terms of the accelerated repayment agreement, conditioned upon closing of the Acquisition, the Company was obligated to pay  $\notin 1,050,000$  (\$1.27 million), the outstanding amount under the repayment agreement, in two tranches as follows:  $\notin 600,000$  (\$726,060) plus accrued interest on January 31, 2015 and  $\notin 450,000$  (\$544,545) on March 31, 2015. The outstanding principal amount for the first and the second tranches, net of capital gain tax withheld, was repaid in full in March 2015 and such next payment was  $\notin 931,312$  (\$1,027,051). The capital gain tax withheld in the amount of  $\notin 118,688$  (\$130,889) was paid on April 9, 2015 and no further amounts were payable in respect of TBG loan. No payments were made during the year ended December 31, 2016.

### 8. Stockholders' Equity

#### **Common Stock**

The Company has authorized 300,000,000 shares of common stock, par value \$0.001 per share. As of December 31, 2016 and 2015, there were 43,058,827 and 39,833,023 shares of common stock issued and outstanding, respectively. As a result of the Acquisition in 2014, the equity structure of Pieris GmbH was retroactively adjusted using the exchange ratio established pursuant to the Acquisition Agreement to reflect the number of shares of the Company issued in the Acquisition.

Each share of the Company's common stock is entitled to one vote and all shares rank equally as to voting and other matters.

Dividends may be declared and paid on the common stock from funds legally available therefor, if, as and when determined by the Board of Directors.

### **Preferred Stock**

The Company has authorized 10,000,000 shares of preferred stock, par value \$0.001 per share. The Company has 4,963 and zero shares of preferred stock issued and outstanding during the years ended December 31, 2016 and 2015, respectively. Shares of preferred stock may be issued in one or more series at such time or times and for such consideration as the Board of Directors may determine.

Each of the 4,963 shares of preferred stock are convertible into one share of the Company's common stock. The stockholders do not have the right to convert any portion of the preferred shares to the extent that they would beneficially own 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect of such conversion. The preferred shares do not have any voting rights. The preferred shares are entitled to receive dividends on a *pari passu* basis with the Company's common stock, when, and if declared. In any liquidation or dissolution of the Company, the Preferred Shares rank senior to the Company's common stock in the distribution of assets, to the extent legally available for distribution.

## **Public Offering**

In July 2015, the Company closed a public offering of an aggregate of 9,090,909 shares of the Company's common stock at a purchase price of \$2.75 per share. All shares of common stock were offered by the Company. On July 24, 2015, the underwriters exercised their over-allotment option to purchase 1,211,827 additional shares of the Company's common stock at the public offering price of \$2.75, the sale of which closed on July 28, 2015.

Gross proceeds raised by the Company in the offering, including the exercise of the over-allotment option, were \$28.3 million and net of equity issuance costs are \$25.8 million. The Company intends to use the net proceeds from the offering to fund research and development, including preclinical and clinical research and development of its drug candidates, working capital and general corporate purposes.

### **Private Placement**

In June 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") for a private placement of the Company's securities with a select group of institutional investors (the "2016 PIPE"). The 2016 PIPE sale transaction, by the Company, consisted of 8,188,804 units at a price of \$2.015 per unit for gross proceeds, to the Company, of approximately \$16.5 million. After deducting for placement agent fees and offering expenses, the aggregate net proceeds from the private placement was approximately \$15.3 million.

Each unit consisted of (i) one share of the Company's Common Stock or non-voting series A convertible preferred stock (the "Series A Convertible Preferred Stock") which are convertible into one share of common stock, (ii) one warrant to purchase 0.4 shares of Common Stock at an exercise price of \$2.00 per share and (iii) one warrant to purchase 0.2 shares of Common Stock at an exercise price of \$3.00 per share. The warrants will be exercisable for a period of five years from the date of issuance. Each share of Series A Convertible Preferred Stock was issued at a price of \$2.015 per share, and is convertible into 1,000 shares of common stock, provided the holder and/or its affiliates do not own greater than 9.99% of the total number of Pieris common stock then outstanding. The Series A Convertible Preferred Stock has no registration or voting rights. In event of a true liquidation or winding down of the business, holders of Series A Convertible Preferred Stock will be paid prior to the holders of Common Stock. In connection with the 2016 PIPE, the Company issued 3,225,804 shares of Common Stock and 4,963 shares of Series A Convertible Preferred Stock to the 2016 PIPE investors.

The Company expects to use the proceeds from the 2016 PIPE towards further development and pre-clinical and clinical work of the Company's proprietary Anticalin product portfolio, including the lead candidates as well as the development of other programs and product candidates, and general corporate purposes.

As a result of the Public Offering, the Consulting Shares (for more information on the Consulting Shares refer to Note 10 *Consulting Shares*) and the 2016 PIPE the Company has 43,058,827 shares of common stock and 4,963 shares of Series A Convertible Preferred Stock issued and outstanding at December 31, 2016.

### 9. Stock and employee benefit plans

In December 2014, the Company adopted the 2014 Employee, Director and Consultant Equity Incentive Plan, (the "2014 Plan") which provides for the grant of stock options to certain designated employees of the Company,

non-employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation Committee of the Board of Directors.

In June 2016, the Company adopted the 2016 Employee, Director and Consultant Equity Incentive Plan, (the "2016 Plan") which provides for the grant of stock options, restricted and unrestricted stock awards, and other stock-based awards to employees of the Company, non-employee directors of the Company, and certain other consultants performing services for the Company as designated by the Compensation Committee of the Board of Directors or the Board of Directors. The 2016 Plan authorizes the issuance of up to 3,750,000 shares of common stock plus a number of additional shares, if awards outstanding under the 2014 Plan are cancelled or expire, to be granted under the 2016 Plan. The 2016 Plan does not provide for an "evergreen" provision. The vesting periods of equity incentives issued under the 2016 Plan are determined by the Compensation Committee of the Company's Board of Directors, with stock options generally vesting over a four-year period.

The Company's stock options have a maximum term of ten years from the date of grant. Stock options granted under the Plans may be either incentive stock options ("ISOs"), or nonqualified stock options. The exercise price of stock options granted under the Plans must be at least equal to the fair market value of the common stock on the date of grant. The Company's general policy is to issue common shares upon the exercise of stock options.

Cash received from option exercises was zero and \$10,000 during the years ended December 31, 2016 and 2015, respectively.

### 2014 Stock Plan

Pieris granted 1,157,734 and 755,329 stock options under the 2014 Plan during the years ended December 31, 2016 and 2015, respectively. Of these stock options granted in the 2015 period, a stock option to purchase 450,000 shares of the Company's common stock, par value \$0.001 (the "Common Stock"), was granted to a newly-hired executive officer subject to certain restrictions on exercise that required the Company's shareholders to approve an increase in the number of shares authorized under the 2014 Plan. Upon the Company's adoption of the 2016 Plan, this stock option was amended and issued under the 2016 Plan; the total shares available under the 2016 Plan reflects the issuance of this option. No compensation expense was recorded for this option in the 2015 period.

The Company granted an option to purchase 500,000 shares outside of the Plan to a newly hired executive officer that was an inducement option, material to the executive officer entering into employment with the Company during the 2015 period. The compensation expense with this inducement option was \$0.3 million and \$0.1 million and is included in research and development expense for the years ended December 31, 2016 and 2015, respectively.

A summary of the status of the Company's 2014 plan as of December 31, 2016 and changes during the year then ended is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2015	2,707,329	\$ 2.05	9.17 years	\$ 741
Granted	1,157,734	1.57		
Forfeited	(140,000)	1.71		
Outstanding, December 31, 2016	3,725,063	\$ 1.91	8.55 years	\$
Vested or expected to vest	3,725,063	<u>\$ 1.91</u>	8.55 years	<u>\$                                    </u>
Exercisable, December 31, 2016	1,961,811	\$ 2.01	7.99 years	\$

Excluded from the table above is the option to purchase 500,000 shares outside of the Plan granted to a newly hired executive officer. The weighted-average exercise price of these options amounts to \$3.36 with a remaining contractual life of 8.63 years.

The 2014 Plan was terminated on June 28, 2016 when the Company adopted its 2016 Plan. Therefore, no options were granted under the 2014 Plan and no options are available for future grant after this date.

#### 2016 Stock Plan

The Company granted 265,313 options to employees and directors under the 2016 Plan during the year ended December 31, 2016. No options were granted during the year ended December 31, 2015. As of December 31, 2016, there were 3,124,687 shares available for future grant under the 2016 Plan. The shares available for future grant under the 2016 Plan include 90,000 shares, which were forfeited during the year ended December 31, 2014 Plan. These forfeited shares were added to the 2016 Plan.

The Company, in 2016, granted an option to purchase 500,000 shares outside of the Plan to a newly hired executive officer that was an inducement option, material to the executive officer entering into employment with the Company during the 2016 period. The compensation expense with this inducement option was \$10,998 and is included in general and administration expense for the year ended December 31, 2016.

A summary of the status of the Company's 2016 plan as of December 31, 2016 and changes during the year then ended is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2015		\$ —	—	\$ —
Granted	715,313	2.36		
Outstanding, December 31, 2016	715,313	\$ 2.36	9.62 years	\$
Vested or expected to vest	715,313	\$ 2.36	9.62 years	\$
Exercisable, December 31, 2016	228,774	\$ 2.46	8.90 years	\$

Excluded from the table above is the option to purchase 500,000 shares outside of the Plan granted to a newly hired executive officer in 2016. The weighted-average exercise price of these options amounts to \$1.45 with a remaining contractual life of 9.91 years.

## 401(k) Savings plan

In 2015, the Company established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. The Company made matching contributions to participants in this plan which totaled \$31,670 and \$3,013 for the years ended December 31, 2016 and 2015, respectively.

### 10. Consulting Shares

# Del Mar Consulting Group & Alex Partners

In March 6 2015, the Company entered into an independent consulting agreement (the "Consulting Agreement") with the Del Mar Consulting Group, Inc. and Alex Partners, LLC (the "Consultants"), pursuant to which the



Company issued 150,000 restricted shares of its common stock (par value \$0.01 per share) to the Consultants (the "Consulting Shares"). The Company agreed to retain the Consultants to provide investor relations consulting to the Company for a period commencing on March 6, 2015 (the "Commencement Date") and ending thirteen months after the Commencement Date (such period, the "Term"). The shares issued in connection with the Consulting Agreement were deemed exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

The terms of the Consulting Agreement state that Pieris has the right to terminate this agreement at any time during the Term of the Consulting Agreement, upon providing Consultants ten days' written notice of the Company's intention to terminate or immediately upon notice in the event of a breach of this agreement by either consultant. If the Company had elected to terminate this agreement for any reason within one hundred eighty days (180) following the effective date each Consultant would have been required to promptly surrender to the Company forty percent (40%) of the number of Consulting Shares issued to it.

The Company uses the Black-Scholes model and estimated the fair value of the 90,000 non-cancellable Consulting Shares to be \$0.3 million based on the closing price per share of \$3.16 as quoted on the OTCQB tier of the OTC Markets Group Inc., or the OTCQB, on the grant date, March 6, 2015. The remaining 60,000 shares were then marked to market based on the Black-Scholes model at each reporting period with the expense being recorded in the consolidated statement of operations as general and administrative expenses.

On September 2, 2015, the remainder of the Consulting Shares vested and the remaining expense was recorded based on the fair value of the shares on that date. The Company recorded expense of \$0.4 million for the non-cancellable and cancellable Consulting Shares for the year ended December 31, 2015. No expenses were recognized during the 2016 period as the remaining shares vested on September 2, 2015 and the remaining expense was recorded based on the fair value of the shares on that date.

### Aquilo Partners

In September 2015, the Company entered into a Letter Agreement (the "Letter Agreement") with Aquilo Partners, L.P. ("Aquilo Partners"). Aquilo Partners has been engaged by the Company as an advisor.

Upon execution of the Letter Agreement, the Company recorded a retainer fee of \$0.1 million. In addition to the cash retainer fee, the Company issued 27,272 shares of the Company's common stock equal in value to \$0.1 million based on the closing price of \$2.75 per share of the Company's common stock on September 4, 2015, the date of the Letter Agreement. The compensation for Aquilo Partners has been recorded in the consolidated statements of operations as general and administrative expenses for the year ended December 31, 2015. No expenses were recognized during the 2016 period.

## Trout Capital LLC

In November 2015, the Company entered into an Agreement with Trout Capital LLC for advisory services. Upon execution of this agreement, Trout Capital was entitled to receive a one-time transaction fee. The Company issued 68,493 shares of the Company's common stock equal in value to \$0.2 million based on the closing price of \$2.19 per share of the Company's common stock on November 20, 2015, the date of the agreement. The compensation for Trout Capital LLC has been recorded in the consolidated statements of operations as general and administrative expenses for the year ended December 31, 2015. No expenses were recognized during the 2016 period

## 11. License and Transfer Agreement

In April 2016, the Company entered into a license and transfer agreement (the "Original Agreement") with Enumeral Biomedical Holdings, Inc. ("Enumeral"), pursuant to which the Company acquired a non-exclusive

worldwide license to use specified patent rights and know-how owned by Enumeral to research, develop and market fusion proteins. As contemplated by the terms of the Original Agreement, the Company entered into a definitive license and transfer agreement (the "Definitive Agreement") with Enumeral on June 6, 2016, to expand the scope of the Company's option to license additional antibodies from Enumeral. Under the Definitive Agreement, Enumeral has granted Pieris options to license two additional undisclosed Enumeral antibodies (each, a "Subsequent Option"); the Subsequent Options expire on May 31, 2017. If Pieris licenses an additional antibody pursuant to a Subsequent Option, Pieris must pay, to Enumeral, an additional undisclosed option exercise payment; any resulting fusion protein products will be subject to royalties and development and sales milestones in the same amounts applicable to the fusion proteins consisting of an Enumeral's PD-1 antibody linked to one or more Anticalin proteins.

Under the terms of the Original Agreement, the Company agreed to pay Enumeral an upfront license fee of \$250,000 upon signing in April 2016 and subsequently elected to pay a \$750,000 maintenance fee in May 2016. The terms of the Definitive Agreement, were essentially unchanged from the Original Agreement. The Company has agreed to pay Enumeral development milestones up to an aggregate of \$37.8 million and sales milestones up to an aggregate of \$67.5 million. Consistent with the terms of the Original Agreement, the Company also agreed to pay Enumeral royalties within a range in the low to lower-middle single digits as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that the Company is required to pay a license fee or royalty to any third party related to the licensed products, the royalty payment due to Enumeral shall be reduced by the amount of such third party fees or payments, up to 50% of the royalty payment for each calendar year due to Enumeral.

The term of the Definitive Agreement ends upon the expiration of the last to expire patent covered under the license. The Definitive Agreement may be terminated by the Company on 30 days notice and by Enumeral upon 60 days notice of a material breach by the Company (or 30 days with respect to a breach of payment obligations by the Company), provided the Company has not caused such breach and dispute resolution procedures specified in the Agreement have been followed.

All amounts paid related to the Agreement have been expensed as research and development expense as incurred. The Company incurred \$1.0 million for year ended December 31, 2016.

## 12. Accrued Expenses

The Company has recorded the following accrued expenses as of December 31, 2016 and December 31, 2015, respectively:

	Years Ended	Years Ended December 31,	
	2016	2015	
Accrued expenses			
Accrued compensation expense	\$1,198,448	\$ 704,597	
Accrued audit and tax fees	454,931	179,223	
Accrued professional fees	867,969	194,790	
Accrued R&D fees	1,040,321	466,076	
Accrued other	157,788	194,694	
Total amount of accrued expenses	3,719,457	1,739,380	

### 13. Related-Party Transactions

### Research and License Agreement with Technische Universität München

On July 4, 2003, the Company entered into the TUM License Agreement, which was subsequently renewed and, on July 26, 2007, superseded and replaced. The agreement established a joint research effort led by Prof. Arne

Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin scaffolds. Prof. Dr. Skerra was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the consolidated financial statements in this report. The Company provided certain funding for TUM research efforts performed under the agreement.

As a result of research efforts to date under the agreement, the Company holds a worldwide exclusive license under its license agreement with TUM to multiple patents and patent applications. The Company bears the costs of filing, prosecution and maintenance of patents assigned or licensed to the Company under the agreement.

As consideration for the assigned patents and licenses above, the Company is required to pay certain development milestones to TUM. The Company is also obliged to pay low-single-digit royalties, including annual minimum royalties, on sales of such products incorporating patented technologies. If the Company grants licenses or sublicenses to those patents to third parties, the Company will be obliged to pay a percentage of the resulting revenue to TUM. The Company's payment obligations are reduced by the Company's proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the TUM License Agreement. The Company can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate the rights in patents assigned to the Company. The Company has incurred expenses related to TUM in connection with the transfer of licenses and protective rights of \$41,791 during the nine-month period ended September 30, 2015. Effective as of the fourth quarter of 2015, Pieris no longer deems TUM a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after the Acquisition. Therefore, no expenses have been incurred during the 2016 period.

The part of the agreement requiring the Company to make payments for research conducted by TUM expired in February 2013 with no further obligations by the Company.

## **EUROCALIN/FP7** Government Grant

TUM is a member of the EUROCALIN consortium and thus is entitled to receive payments under the grant agreement for research activities. Research activities are carried out by Prof. Dr. Skerra, who was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the financial statements in this report. As Pieris AG was transformed to Pieris GmbH, the change in legal entity removed the requirement of having a supervisory board; accordingly, Prof. Dr. Skerra no longer holds a seat on the supervisory board. The government grant agreement with FP7 is further discussed in Note 3—Revenue.

### Consulting Contract between Prof. Dr. Arne Skerra and the Company

In 2001, the Company entered into a Consulting Agreement with Prof. Dr. Skerra, pursuant to which Prof. Dr. Skerra provides advice regarding the use of new proteins, in particular Anticalin proteins and antibodies, for the purpose of research and development. The Consulting Agreement has an unlimited term but can be terminated by the Company upon three months' notice with effect from the end of a month and by Prof. Dr. Skerra upon one year's notice with effect from the end of a year. Under the Consulting Agreement, the Company incurred and paid to Prof. Dr. Skerra consulting fees of \$16,717 during the nine months ended September 30, 2015. As of the fourth quarter of 2015 Pieris no longer deems Prof. Dr. Skerra a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after the Acquisition. Therefore, no expenses have been incurred during the 2016 period.

## 14. Commitments and Contingencies

#### **Licensing Commitments**

The Company has license agreements with three parties under which the Company is obliged to pay annual license fees. One agreement, between IBA GmbH and the Company, requires annual license payments of \$32,718 and relates to licenses for Strep-tag technology that represent tool technologies used for research purposes only. The agreement expires in 2024.

The second license agreement is between TUM and the Company (see Note 13 *Related-Party Transactions*). Under this agreement, the Company is obliged to pay a minimum annual license fee of \$0.1 million to TUM. The agreement expires in 2027.

The table below shows the minimum annual license fee commitments under the two agreements as of December 31, 2016:

	License
	payments
2017	\$ 84,124
2018	84,124
2019	84,124
2020	84,124
2021	84,124
Thereafter	410,105
Total minimum license payments	\$830,725

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#### Leases

The Company leases office and laboratory space in Freising, Germany. The first lease agreement has a defined termination date, which is the end of a notification period of eight months at the end of each quarter. In June 2016, we entered into a second lease agreement for additional office space in Freising, which has a fixed term of one year. As we have not cancelled this lease agreement by December 12, 2016, the term of the lease extended by one year until June 2018. On August 27, 2015, the Company entered into an Agreement of Sublease (the "Sublease Agreement") with Berenberg Capital Markets LLC (the "Sublandlord"). Under the Sublease Agreement, the Sublandlord will sublease to the Company approximately 3,950 square feet in Boston, MA. The term of the lease will expire on February 27, 2022. The Sublease Agreement provides free rent for the first two months in addition to scheduled rent increases that are not dependent on future events.

The Company records rent expense on a straight-line basis over the lease term period. For the years ended December 31, 2016 and 2015 respectively, the Company has recognized rent expense in an amount of \$0.2 million and \$18,399 under the Sublease Agreement. Rent expense under the Company's operating lease for its Freising, Germany based facility was \$0.3 million and \$0.4 million for the years ended December 31, 2016 and 2015, respectively.

The Company's contractual commitments of the non-cancellable portion under theses operating leases as of December 31, 2016 are as follows:

		Total
2017	\$	391,042
2018		209,590
2019		195,909
2020		199,859
2021		203,809
Thereafter		34,563
Total minimum lease payments	\$1	,234,772

### 15. Subsequent Events

### License and Collaboration Agreement

On January 4, 2017, Pieris entered into a License and Collaboration Agreement (the "Collaboration Agreement") and a Non-Exclusive Anticalin Platform Technology License Agreement (the "License Agreement" and together with the Collaboration Agreement, the "Agreements") with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, "Servier"), pursuant to which Pieris and Servier will initially pursue five bispecific therapeutic programs, led by Pieris' PRS-332 program, a PD-1-targeting bispecific checkpoint inhibitor. Pieris and Servier will jointly develop PRS-332 and split commercial rights geographically, with Pieris retaining all commercial rights in the United States and Servier having commercial rights in the rest of the world. The four additional committed programs have been defined, which may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on Pieris' proprietary platform to generate innovative immuno-oncology bispecific drug candidates. The collaboration may be expanded by up to three additional therapeutic programs. Pieris has the option to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332, while Servier will be responsible for development and commercialization of the other programs worldwide.

Under the Agreements, Pieris will receive an upfront payment of  $\notin$ 30.0 million (approximately \$31.3 million). Pieris may also receive FTE funding for specific projects, as well as development-dependent and commercial milestone payments for PRS-332 and each additional program. The total development, regulatory, and sales-based milestone payments to Pieris could exceed  $\notin$ 1.7 billion (approximately \$1.8 billion) over the life of the collaboration and are dependent on the final number of projects pursued and the number of co-development options exercised by Pieris. Pieris and Servier will share preclinical and clinical development costs for each co-developed program. In addition, Pieris will be entitled to receive tiered royalties up to low double digits on the sales of commercialized products in the Servier territories.

The term of each Agreement ends upon the expiration of all of Servier's payment obligations under such Agreement. The Agreements may be terminated by Servier for convenience beginning 12 months after their effective date upon 180 days' notice. The Agreements may also be terminated by Servier or Pieris for material breach upon 90 days or 120 days notice of a material breach, with respect to the Collaboration Agreement and License Agreement, respectively, provided that the applicable party has not cured such breach by the applicable 90-day or 120-day permitted cure period, and dispute resolution procedures specified in the applicable Agreement have been followed. The Agreements may also be terminated due to the other party's insolvency or for a safety issue and may in certain instances be terminated on a product-by-product and/or country-by-country basis. The License Agreement will terminate upon termination of the Collaboration Agreement, on a product-by-product and/or country-by-country basis.

### **Option Agreement**

On February 27, 2017, Pieris entered into an Exclusive Option Agreement (the "Option Agreement") with ASKA Pharmaceutical Co. Ltd. ("ASKA"), pursuant to which ASKA will have an exclusive option to obtain an exclusive license to develop and commercialize Pieris' PRS-080 drug candidate targeting hepcidin in Japan and certain other Asian markets.

Under the terms of the Option Agreement, Pieris will receive an option payment of \$2.75 million USD from ASKA. Following an analysis period after completion of the planned Phase 2a study of PRS-080 in dialysis-dependent anemia patients to be conducted by Pieris, ASKA may exercise its option to obtain an exclusive license to develop and commercialize PRS-080 in Japan, South Korea and certain other Asian markets (excluding China). Should ASKA exercise the option, Pieris would be eligible for more than \$80 million USD in combined option exercise fee and milestone payments associated with development and commercialization of PRS-080 in the first indication in Japan. Pieris may receive further development milestones in additional indications, as well as in other countries within the ASKA territory. Pieris may also receive double-digit royalties on net sales of PRS-080 in the licensed territory up to the mid- to high-teens.

The term of the Option Agreement, including the option rights granted therein, ends on the earlier of (i) ASKA's written notice to Pieris of ASKA's decision not to exercise the option rights granted under the Option Agreement, (ii) ASKA's failure to exercise its option rights within sixty (60) days after the final results of the phase 2a study are made available to ASKA, (iii) three (3) months from date on which Pieris delivers to ASKA the final results of the phase 2a study in the European Union, or (iv) Pieris and ASKA's execution of the definitive agreements granting ASKA licenses to develop and commercialize PRS-080 in the Japan, South Korea and certain other Asian countries as contemplated under the Option Agreement.

Option No.

## PIERIS PHARMACEUTICALS, INC.

**Stock Option Grant Notice** 

Stock Option Grant under the Company's 2016 Employee, Director and Consultant Equity Incentive Plan

1.	Name and Address of Participant:	
	-	
2.	Date of Option Grant:	
3.	Type of Grant:	
4.	Maximum Number of Shares for which this Option is exercisable:	
5.	Exercise (purchase) price per share:	
6.		
7.	Vesting Start Date:	

8. Vesting Schedule: This Option shall become exercisable (and the Shares issued upon exercise shall be vested) as follows provided the Participant is an Employee, director or Consultant of the Company or of an Affiliate on the applicable vesting date:

## [Insert Vesting Schedule]

The foregoing rights are cumulative and are subject to the other terms and conditions of this Agreement and the Plan.

The Company and the Participant acknowledge receipt of this Stock Option Grant Notice and agree to the terms of the Stock Option Agreement attached hereto and incorporated by reference herein, the Company's 2016 Employee, Director and Consultant Equity Incentive Plan and the terms of this Option Grant as set forth above.

## PIERIS PHARMACEUTICALS, INC.

By:

Participant

#### PIERIS PHARMACEUTICALS, INC.

#### **STOCK OPTION AGREEMENT - INCORPORATED TERMS AND CONDITIONS**

AGREEMENT made as of the date of grant set forth in the Stock Option Grant Notice by and between Pieris Pharmaceuticals, Inc. (the "Company"), a Nevada corporation, and the individual whose name appears on the Stock Option Grant Notice (the "Participant").

WHEREAS, the Company desires to grant to the Participant an Option to purchase shares of its common stock, \$0.001 par value per share (the "Shares"), under and for the purposes set forth in the Company's 2016 Employee, Director and Consultant Equity Incentive Plan (the "Plan");

WHEREAS, the Company and the Participant understand and agree that any terms used and not defined herein have the same meanings as in the Plan; and

WHEREAS, the Company and the Participant each intend that the Option granted herein shall be of the type set forth in the Stock Option Grant Notice.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and for other good and valuable consideration, the parties hereto agree as follows:

## 1. GRANT OF OPTION.

The Company hereby grants to the Participant the right and option to purchase all or any part of an aggregate of the number of Shares set forth in the Stock Option Grant Notice, on the terms and conditions and subject to all the limitations set forth herein, under United States securities and tax laws, and in the Plan, which is incorporated herein by reference. The Participant acknowledges receipt of a copy of the Plan.

#### 2. EXERCISE PRICE.

The exercise price of the Shares covered by the Option shall be the amount per Share set forth in the Stock Option Grant Notice, subject to adjustment, as provided in the Plan, in the event of a stock split, reverse stock split or other events affecting the holders of Shares after the date hereof (the "Exercise Price"). Payment shall be made in accordance with Paragraph 9 of the Plan.

### 3. EXERCISABILITY OF OPTION.

Subject to the terms and conditions set forth in this Agreement and the Plan, the Option granted hereby shall become vested and exercisable as set forth in the Stock Option Grant Notice and is subject to the other terms and conditions of this Agreement and the Plan.

### 4. <u>TERM OF OPTION</u>.

This Option shall terminate on the Option Expiration Date as specified in the Stock Option Grant Notice and, if this Option is designated in the Stock Option Grant Notice as an ISO and the Participant owns as of the date hereof more than 10% of the total combined voting power of all classes of capital stock of the Company or an Affiliate, such date may not be more than five years from the date of this Agreement, but shall be subject to earlier termination as provided herein or in the Plan.

If the Participant ceases to be an Employee, director or Consultant of the Company or of an Affiliate for any reason other than the death or Disability of the Participant, or termination of the Participant for Cause (the "Termination Date"), the Option to the extent then vested and exercisable pursuant to Section 3 hereof as of the Termination Date, and not previously terminated in accordance with this Agreement, may be exercised within three months after the Termination Date, or on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice, whichever is earlier, but may not be exercised thereafter except as set forth below. In such event, the unvested portion of the Option shall not be exercisable and shall expire and be cancelled on the Termination Date.

If this Option is designated in the Stock Option Grant Notice as an ISO and the Participant ceases to be an Employee of the Company or of an Affiliate but continues after termination of employment to provide service to the Company or an Affiliate as a director or Consultant, this Option shall continue to vest in accordance with Section 3 above as if this Option had not terminated until the Participant is no longer providing services to the Company. In such case, this Option shall automatically convert and be deemed a Non-Qualified Option as of the date that is three months from termination of the Participant's employment and this Option shall continue on the same terms and conditions set forth herein until such Participant is no longer providing service to the Company or an Affiliate.

Notwithstanding the foregoing, in the event of the Participant's Disability or death within three months after the Termination Date, the Participant or the Participant's Survivors may exercise the Option within one year after the Termination Date, but in no event after the Option Expiration Date as specified in the Stock Option Grant Notice.

In the event the Participant's service is terminated by the Company or an Affiliate for Cause, the Participant's right to exercise any unexercised portion of this Option even if vested shall cease immediately as of the time the Participant is notified his or her service is terminated for Cause, and this Option shall thereupon terminate. Notwithstanding anything herein to the contrary, if subsequent to the Participant's termination, but prior to the exercise of the Option, the Administrator determines that, either prior or subsequent to the Participant's termination, the Participant engaged in conduct which would constitute Cause, then the Participant shall immediately cease to have any right to exercise the Option and this Option shall thereupon terminate.

In the event of the Disability of the Participant, as determined in accordance with the Plan, the Option shall be exercisable within one year after the Participant's termination of

service due to Disability or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

- (a) to the extent that the Option has become exercisable but has not been exercised as of the date of the Participant's termination of service due to Disability; and
- (b) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of the Participant's termination of service due to Disability of any additional vesting rights that would have accrued on the next vesting date had the Participant not become Disabled. The proration shall be based upon the number of days accrued in the current vesting period prior to the date of the Participant's termination of service due to Disability.

In the event of the death of the Participant while an Employee, director or Consultant of the Company or of an Affiliate, the Option shall be exercisable by the Participant's Survivors within one year after the date of death of the Participant or, if earlier, on or prior to the Option Expiration Date as specified in the Stock Option Grant Notice. In such event, the Option shall be exercisable:

- (x) to the extent that the Option has become exercisable but has not been exercised as of the date of death; and
- (y) in the event rights to exercise the Option accrue periodically, to the extent of a pro rata portion through the date of death of any additional vesting rights that would have accrued on the next vesting date had the Participant not died. The proration shall be based upon the number of days accrued in the current vesting period prior to the Participant's date of death.

## 5. METHOD OF EXERCISING OPTION.

Subject to the terms and conditions of this Agreement, the Option may be exercised by written notice to the Company or its designee, in substantially the form of <u>Exhibit A</u> attached hereto (or in such other form acceptable to the Company, which may include electronic notice). Such notice shall state the number of Shares with respect to which the Option is being exercised and shall be signed by the person exercising the Option (which signature may be provided electronically in a form acceptable to the Company). Payment of the Exercise Price for such Shares shall be made in accordance with Paragraph 9 of the Plan. The Company shall deliver such Shares as soon as practicable after the notice shall be received, provided, however, that the Company may delay issuance of such Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law (including, without limitation, state securities or "blue sky" laws). The Shares as to which the Option shall have been so exercised shall be registered in the Company's share register in the name of the person so exercising the Option (or, if the Option shall be exercised by the Participant and if the Participant shall so request in the notice exercising the Option, shall be registered in the

Company's share register in the name of the Participant and another person jointly, with right of survivorship) and shall be delivered as provided above to or upon the written order of the person exercising the Option. In the event the Option shall be exercised, pursuant to Section 4 hereof, by any person other than the Participant, such notice shall be accompanied by appropriate proof of the right of such person to exercise the Option. All Shares that shall be purchased upon the exercise of the Option as provided herein shall be fully paid and nonassessable.

### 6. <u>PARTIAL EXERCISE</u>.

Exercise of this Option to the extent above stated may be made in part at any time and from time to time within the above limits, except that no fractional share shall be issued pursuant to this Option.

## 7. <u>NON-ASSIGNABILITY</u>.

The Option shall not be transferable by the Participant otherwise than by will or by the laws of descent and distribution. If this Option is a Non-Qualified Option then it may also be transferred pursuant to a qualified domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act or the rules thereunder. Except as provided above in this paragraph, the Option shall be exercisable, during the Participant's lifetime, only by the Participant (or, in the event of legal incapacity or incompetency, by the Participant's guardian or representative) and shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of the Option or of any rights granted hereunder contrary to the provisions of this Section 7, or the levy of any attachment or similar process upon the Option shall be null and void.

### 8. NO RIGHTS AS STOCKHOLDER UNTIL EXERCISE.

The Participant shall have no rights as a stockholder with respect to Shares subject to this Agreement until registration of the Shares in the Company's share register in the name of the Participant. Except as is expressly provided in the Plan with respect to certain changes in the capitalization of the Company, no adjustment shall be made for dividends or similar rights for which the record date is prior to the date of such registration.

## 9. ADJUSTMENTS.

The Plan contains provisions covering the treatment of Options in a number of contingencies such as stock splits and mergers. Provisions in the Plan for adjustment with respect to stock subject to Options and the related provisions with respect to successors to the business of the Company are hereby made applicable hereunder and are incorporated herein by reference.

# 10. <u>TAXES</u>.

The Participant acknowledges that any income or other taxes due from him or her with respect to this Option or the Shares issuable pursuant to this Option shall be the Participant's responsibility. The Participant acknowledges and agrees that (i) the Participant was free to use professional advisors of his or her choice in connection with this Agreement, has received advice from his or her professional advisors in connection with this Agreement, understands its meaning and import, and is entering into this Agreement freely and without coercion or duress; (ii) the Participant has not received and is not relying upon any advice, representations or assurances made by or on behalf of the Company or any Affiliate or any employee of or counsel to the Company or any Affiliate regarding any tax or other effects or implications of the Option, the Shares or other matters contemplated by this Agreement; and (iii) neither the Administrator, the Company, its Affiliates, nor any of its officers or directors, shall be held liable for any applicable costs, taxes, or penalties associated with the Option if, in fact, the Internal Revenue Service were to determine that the Option constitutes deferred compensation under Section 409A of the Code.

If this Option is designated in the Stock Option Grant Notice as a Non-Qualified Option or if the Option is an ISO and is converted into a Non-Qualified Option and such Non-Qualified Option is exercised, the Participant agrees that the Company may withhold from the Participant's remuneration, if any, the minimum statutory amount of federal, state and local withholding taxes attributable to such amount that is considered compensation includable in such person's gross income. At the Company's discretion, the amount required to be withheld may be withheld in cash from such remuneration, or in kind from the Shares otherwise deliverable to the Participant on exercise of the Option. The Participant further agrees that, if the Company does not withhold an amount from the Participant's remuneration sufficient to satisfy the Company's income tax withholding obligation, the Participant will reimburse the Company on demand, in cash, for the amount under-withheld.

### 11. PURCHASE FOR INVESTMENT.

Unless the offering and sale of the Shares to be issued upon the particular exercise of the Option shall have been effectively registered under the Securities Act, the Company shall be under no obligation to issue the Shares covered by such exercise unless the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act and until the following conditions have been fulfilled:

(a) The person(s) who exercise the Option shall warrant to the Company, at the time of such exercise, that such person(s) are acquiring such Shares for their own respective accounts, for investment, and not with a view to, or for sale in connection with, the distribution of any such Shares, in which event the person(s) acquiring such Shares shall be bound by the provisions

of the following legend which shall be endorsed upon any certificate(s) evidencing the Shares issued pursuant to such exercise:

"The shares represented by this certificate have been taken for investment and they may not be sold or otherwise transferred by any person, including a pledgee, unless (1) either (a) a Registration Statement with respect to such shares shall be effective under the Securities Act of 1933, as amended, or (b) the Company shall have received an opinion of counsel satisfactory to it that an exemption from registration under such Act is then available, and (2) there shall have been compliance with all applicable state securities laws;" and

(b) If the Company so requires, the Company shall have received an opinion of its counsel that the Shares may be issued upon such particular exercise in compliance with the Securities Act without registration thereunder. Without limiting the generality of the foregoing, the Company may delay issuance of the Shares until completion of any action or obtaining of any consent, which the Company deems necessary under any applicable law (including without limitation state securities or "blue sky" laws).

## 12. RESTRICTIONS ON TRANSFER OF SHARES.

12.1 The Participant agrees that in the event the Company proposes to offer for sale to the public any of its equity securities and such Participant is requested by the Company and any underwriter engaged by the Company in connection with such offering to sign an agreement restricting the sale or other transfer of Shares, then it will promptly sign such agreement and will not transfer, whether in privately negotiated transactions or to the public in open market transactions or otherwise, any Shares or other securities of the Company held by him or her during such period as is determined by the Company and the underwriters, not to exceed 180 days following the closing of the offering, plus such additional period of time as may be required to comply with Marketplace Rule 2711 of the National Association of Securities Dealers, Inc. or similar rules thereto (such period, the "Lock-Up Period"). Such agreement shall be in writing and in form and substance reasonably satisfactory to the Company and such underwriter and pursuant to customary and prevailing terms and conditions. Notwithstanding whether the Participant has signed such an agreement, the Company may impose stop-transfer instructions with respect to the Shares or other securities of the Company subject to the foregoing restrictions until the end of the Lock-Up Period.

12.2 The Participant acknowledges and agrees that neither the Company, its stockholders nor its directors and officers, has any duty or obligation to disclose to the Participant any material information regarding the business of the Company or affecting the value of the Shares before, at the time of, or following a termination of the service of the Participant by the Company, including, without limitation, any information concerning plans for the Company to make a public offering of its securities or to be acquired by or merged with or into another firm or entity.

#### 13. NO OBLIGATION TO MAINTAIN RELATIONSHIP.

The Participant acknowledges that: (i) the Company is not by the Plan or this Option obligated to continue the Participant as an employee, director or Consultant of the Company or an Affiliate; (ii) the Plan is discretionary in nature and may be suspended or terminated by the Company at any time; (iii) the grant of the Option is a one-time benefit which does not create any contractual or other right to receive future grants of options, or benefits in lieu of options; (iv) all determinations with respect to any such future grants, including, but not limited to, the times when options shall be granted, the number of shares subject to each option, the option price, and the time or times when each option shall be exercisable, will be at the sole discretion of the Company; (v) the Participant's participation in the Plan is voluntary; (vi) the value of the Option is an extraordinary item of compensation which is outside the scope of the Participant's employment or consulting contract, if any; and (vii) the Option is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits or similar payments.

### 14. IF OPTION IS INTENDED TO BE AN ISO.

If this Option is designated in the Stock Option Grant Notice as an ISO so that the Participant (or the Participant's Survivors) may qualify for the favorable tax treatment provided to holders of Options that meet the standards of Section 422 of the Code then any provision of this Agreement or the Plan which conflicts with the Code so that this Option would not be deemed an ISO is null and void and any ambiguities shall be resolved so that the Option qualifies as an ISO. The Participant should consult with the Participant's own tax advisors regarding the tax effects of the Option and the requirements necessary to obtain favorable tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements.

Notwithstanding the foregoing, to the extent that the Option is designated in the Stock Option Grant Notice as an ISO and is not deemed to be an ISO pursuant to Section 422(d) of the Code because the aggregate Fair Market Value (determined as of the Date of Option Grant) of any of the Shares with respect to which this ISO is granted becomes exercisable for the first time during any calendar year in excess of \$100,000, the portion of the Option representing such excess value shall be treated as a Non-Qualified Option and the Participant shall be deemed to have taxable income measured by the difference between the then Fair Market Value of the Shares received upon exercise and the price paid for such Shares pursuant to this Agreement.

Neither the Company nor any Affiliate shall have any liability to the Participant, or any other party, if the Option (or any part thereof) that is intended to be an ISO is not an ISO or for any action taken by the Administrator, including without limitation the conversion of an ISO to a Non-Qualified Option.

## 15. NOTICE TO COMPANY OF DISQUALIFYING DISPOSITION OF AN ISO.

If this Option is designated in the Stock Option Grant Notice as an ISO then the Participant agrees to notify the Company in writing immediately after the Participant makes a



Disqualifying Disposition of any of the Shares acquired pursuant to the exercise of the ISO. A Disqualifying Disposition is defined in Section 424(c) of the Code and includes any disposition (including any sale) of such Shares before the later of (a) two years after the date the Participant was granted the ISO or (b) one year after the date the Participant acquired Shares by exercising the ISO, except as otherwise provided in Section 424(c) of the Code. If the Participant has died before the Shares are sold, these holding period requirements do not apply and no Disqualifying Disposition can occur thereafter.

## 16. NOTICES.

Any notices required or permitted by the terms of this Agreement or the Plan shall be given by recognized courier service, facsimile, registered or certified mail, return receipt requested, addressed as follows:

If to the Company:

Pieris Pharmaceuticals, Inc. Lise-Meitner-Strasse 30 85354 Freising-Weihenstephan Germany Telephone No.: +49 (0) 8161 14 11 400 1 Facsimile No.: +49 (0) 8161 14 11 444 Attention: Chief Executive Officer

If to the Participant, at the address set forth on the Stock Option Grant Notice.

or to such other address or addresses of which notice in the same manner has previously been given. Any such notice shall be deemed to have been given upon the earlier of receipt, one business day following delivery to a recognized courier service or three business days following mailing by registered or certified mail.

## 17. GOVERNING LAW.

This Agreement shall be governed by and construed in accordance with the laws of Nevada, without giving effect to the conflict of law principles thereof. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction in Nevada and agree that such litigation shall be conducted in the state courts of Nevada or the federal courts of the United States for the District of Nevada.

# 18. BENEFIT OF AGREEMENT.

Subject to the provisions of the Plan and the other provisions hereof, this Agreement shall be for the benefit of and shall be binding upon the heirs, executors, administrators, successors and assigns of the parties hereto.

# 19. ENTIRE AGREEMENT.

This Agreement, together with the Plan, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement not expressly set forth in this Agreement shall affect or be used to interpret, change or restrict, the express terms and provisions of this Agreement, provided, however, in any event, this Agreement shall be subject to and governed by the Plan.

#### 20. MODIFICATIONS AND AMENDMENTS.

The terms and provisions of this Agreement may be modified or amended as provided in the Plan.

## 21. WAIVERS AND CONSENTS.

Except as provided in the Plan, the terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

### 22. DATA PRIVACY.

By entering into this Agreement, the Participant: (i) authorizes the Company and each Affiliate, and any agent of the Company or any Affiliate administering the Plan or providing Plan recordkeeping services, to disclose to the Company or any of its Affiliates such information and data as the Company or any such Affiliate shall request in order to facilitate the grant of options and the administration of the Plan; and (ii) authorizes the Company and each Affiliate to store and transmit such information in electronic form for the purposes set forth in this Agreement.

#### [REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

## NOTICE OF EXERCISE OF STOCK OPTION

### [Form for Shares registered in the United States]

To: Pieris Pharmaceuticals, Inc.

IMPORTANT NOTICE: This form of Notice of Exercise may only be used at such time as the Company has filed a Registration Statement with the Securities and Exchange Commission under which the issuance of the Shares for which this exercise is being made is registered and such Registration Statement remains effective.

Ladies and Gentlemen:

I hereby exercise my Stock Option to purchase \_\_\_\_\_\_ shares (the "Shares") of the common stock, \$0.001 par value, of Pieris Pharmaceuticals, Inc. (the "Company"), at the exercise price of \$\_\_\_\_\_ per share, pursuant to and subject to the terms of that Stock Option Grant Notice dated \_\_\_\_\_, 201\_.

I understand the nature of the investment I am making and the financial risks thereof. I am aware that it is my responsibility to have consulted with competent tax and legal advisors about the relevant national, state and local income tax and securities laws affecting the exercise of the Option and the purchase and subsequent sale of the Shares.

I am paying the option exercise price for the Shares as follows:

Please issue the Shares (check one):

 $\Box$  to me; or

□ to me and \_\_\_\_\_, as joint tenants with right of survivorship,

at the following address:

Exhibit A-1

My mailing address for stockholder communications, if different from the address listed above, is:

Very truly yours,

Participant (signature)

Print Name

Date

Exhibit A-2

## AMENDMENT NO. 1 TO DEFINITIVE LICENSE AND TRANSFER AGREEMENT

This Amendment No. 1 to Definitive License and Transfer Agreement (this "**Amendment**"), effective as of January 3, 2017 (the "**Amendment Effective Date**"), is by and between Enumeral Biomedical Holdings, Inc., a Delaware corporation with a place of business at 200 Cambridge Park Drive, Suite 2000, Cambridge, MA 02140 ("**Enumeral**") and Pieris Pharmaceuticals, Inc., a Nevada corporation with a place of business at 255 State Street, 9th Floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a German company with a place of business at Lise-Meitner-Strasse 30, 85354 Freising, Germany (collectively, and together with their Affiliates, "**Pieris**"), under which the Parties mutually agree to modify and amend the Definitive License and Transfer Agreement between the Parties, with an Effective Date of June 6, 2016 (the "**Agreement**"), as set forth below. Capitalized terms used in the Amendment but not defined herein shall have the meanings set forth in the Agreement.

WHEREAS, under the Agreement, Enumeral granted Pieris a non-exclusive right and license under certain Enumeral IP granting Pieris the right to exploit such Enumeral IP, including through the grant of sublicenses, subject to certain restrictions; and

WHEREAS, the Parties hereto wish to amend the terms of the Agreement to protect the Sublicensee's rights in the event the Agreement is terminated for any reason.

NOW THEREFORE, the parties hereby agree as follows:

- 1. <u>Amendments</u>. The Agreement is hereby amended as follows:
- 1.1. The following sentence shall be added to the end of Section 2.4 (Sublicenses) as a new sentence: "Pieris shall furnish Enumeral with a true and accurate fully executed copy of any Sublicense and any amendments thereto or default letters thereto, promptly after its or their execution. Pieris may keep confidential product targets, development plans, patent numbers, the royalty percentage amounts, the amounts of any upfront, milestone or option payments, and the percentage amount applied to any sublicense or similar economic terms from the Sublicense and any amendments thereto."

#### 1.2. <u>The following is added to Section 9.5</u> (Effect of Termination):

### b) Sublicenses.

(i) Any sublicense agreement(s) entered into under Section 2.4 of this Agreement for the purpose of the development and commercialization of any drug or products (each, a "Sublicense") in effect as of the effective date of termination of this Agreement shall terminate (the "Termination Date"), and such Sublicensee shall, at its option by providing written notice of its election to do so within forty-five (45) days following the Termination Date, be a direct licensee under and subject to the terms and conditions of this Agreement as if a signatory hereto, provided that: (i) the payment terms of the direct license will be those of this Agreement; (ii) the Sublicensee is in good standing with respect to the Sublicense and was not itself the cause of the termination of this Agreement; (iii) the rights granted to the Sublicensee shall be subject to the field restrictions and other limitations under the Sublicense as if fully set forth herein; (iv) Enumeral and Sublicensee shall negotiate in good faith regarding the choice of law jurisdiction for such direct license; (v) any diligence requirements on the part of such Sublicensee for the development of any product under the Sublicense Agreement shall continue in addition to any diligence requirements under this Agreement; (vi) such Sublicensee has expressly agreed to abide by this provision and assume the obligations under this Agreement; license between Enumeral and the

Sublicensee shall not place any additional obligations or restrictions (including but not limited to representations, warranties, or liabilities) on Enumeral that are not included in this Agreement or that are beyond Enumeral's obligations under this Agreement without the prior written consent of Enumeral. By accepting such direct license, such Sublicensee releases Enumeral from any claim or liability whether actual or contingent under any agreement with Pieris.

(ii) In the event that a Sublicense of any license granted to Pieris under this Agreement is terminated or rejected by or on behalf of Pieris under the applicable provisions of any bankruptcy laws and Sublicensee is unable to make an election thereunder to continue the Sublicense, then Enumeral hereby grants a direct license to Sublicensee under the terms of Section 9.5(b)(i) above, without any further action of Pieris, provided that such action is not blocked or objected to in bankruptcy court, and further provided that this Agreement is concurrently terminated in such bankruptcy action (or, if the Agreement is not so terminated, Pieris hereby waives any restrictions to the contrary in the Agreement in order to permit such direct license).

(iii) The Parties further acknowledge and agree that any such Sublicensee shall be a third party beneficiary of this Agreement to the extent required to enforce its rights under this Section 9.5(b).

2. <u>Scope</u>. This Amendment supersedes all proposals, negotiations, conversations and/or discussions between or among Parties relating to the subject matter of this Amendment and all past dealing or industry custom. This Amendment shall be integrated in and form part of the Agreement effective as of the Amendment Effective Date. Except for the foregoing modifications, the Agreement is hereby ratified and confirmed in accordance with its original terms. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

## ENUMERAL BIOMEDICAL HOLDINGS, INC.

By: /s/ Matthew A. Ebert Title: General Counsel

Date: January 3, 2017

## PIERIS PHARMACEUTICALS, INC.

By: /s/ Stephen S. Yoder Title: President and CEO

Date: January 3, 2017

### PIERIS PHARMACEUTICALS GMBH

By: /s/ Stephen S. Yoder Title: Managing Director

Date: January 3, 2017

### Exhibit 10.15

Confidential [\*\*\*]

## LICENSE AND COLLABORATION AGREEMENT

### BETWEEN

# LES LABORATOIRES SERVIER

## INSTITUT DE RECHERCHES INTERNATIONALES SERVIER

### AND

# PIERIS PHARMACEUTICALS, INC.

# PIERIS PHARMACEUTICALS GMBH

#### License and Collaboration Agreement

This License and Collaboration Agreement is entered into as of January 4, 2017 (the "*Effective Date*") by and between Les Laboratoires Servier, a corporation incorporated under the laws of France having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France and Institut de Recherches Internationales Servier, a company duly organized and existing under the laws of France having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France (individually and collectively, "*Servier*"), and Pieris Pharmaceuticals, Inc., a Nevada corporation having offices and principal place of business at 255 State Street, 9th floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a company organized and existing under the laws of Germany having offices and principal place of business at Lise-Meitner-str. 30, 85354 Freising, Germany (individually and collectively, "*Pieris*"). Servier and Pieris are individually referred to herein as a "*Party*" and collectively, as the "*Parties*".

## RECITALS

WHEREAS, Pieris and its Affiliates own or control the proprietary, lipocalin-derived Anticalin<sup>®</sup> technology and have developed other products and technologies that can be used to develop bispecific products, and own or control certain patents, proprietary technology, know-how and information relating to such products or technologies;

**WHEREAS**, Servier and its Affiliates also own or control certain products or technologies that can be used to develop bispecific products and possess expertise in developing, manufacturing and commercializing pharmaceutical products;

WHEREAS, Servier wishes to obtain a license to, and Pieris wishes to license to Servier, certain patents and know-how, in order for Servier to research, Develop, Manufacture and Commercialize the Lead Product (capitalized terms as defined below) in accordance with this Agreement ("*Lead Product Project*"); and

**WHEREAS**, the Parties desire to each grant to the other, and the other Party wishes to obtain, a license to certain of such granting Party's patents and know-how in order to collaboratively generate, evaluate, research, Develop, Manufacture and Commercialize certain novel Collaboration Products (as defined below) in accordance with this Agreement and the Platform Agreement.

#### Confidential

# CONFIDENTIAL TREATMENT REQUESTED

**NOW, THEREFORE**, in consideration of the promises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### **ARTICLE 1 DEFINITIONS**

**Defined Terms**. The following capitalized terms or derivatives thereof (verbs, nouns, singular, plural), when used in this Agreement, shall have the following meanings:

1.1 "Access Notice" has the meaning set forth in Section 2.6.2.

1.2 "*Accounting Standards*" means the International Financial Reporting Standards, the US Generally Accepted Accounting Principles, and any other internationally recognized accounting standards that may be adopted by a Party.

1.3 "Acquired Competing Product" has the meaning set forth in Section 6.2.2.

1.4 "Acquisition Transaction" has the meaning set forth in Section 6.2.2.

1.5 "Acquiree" has the meaning set forth in Section 6.2.2.

1.6 "Acquiror" has the meaning set forth in Section 6.2.2.

1.7 "Additional Collaboration Effective Date" means the date that is agreed upon by the Parties in good faith following the date of exercise of the Servier Collaboration Option by Servier pursuant to <u>Section 3.1.1.(c)</u> but no later than within one (1) month following the date of exercise of the Servier Collaboration Option.

1.8 "Additional Collaboration Products" has the meaning set forth in Section 3.1.1.(d).

1.9 "Additional Research Collaboration" has the meaning set forth in Section 3.1.1.(c).

1.10 "Additional Research Collaboration Development Funds" has the meaning set forth in Section 3.1.6.(a)(i).

1.11 "Additional Research Collaboration Initial Term" has the meaning set forth in Section 3.1.1.(c).

1.12 "Additional Research Collaboration Renewal Term" has the meaning set forth in Section 3.1.1.(c).

1.13 *"Additional Research Collaboration Term*" means the Additional Research Collaboration Initial Term together with all Additional Research Collaboration Renewal Terms, if any.

1.14 "Additional Study Data" has the meaning set forth in Section 2.3.4.(a).

1.15 "*ADPIC Treaty*" has the meaning set forth in <u>Section 8.1</u>.

3

1.16 "*Affiliate*" means with respect to a Party, any person or entity, which directly or indirectly controls, is controlled by, or is under common control with such Party. Solely as used in this definition, the term "control" means (a) the ownership, directly or indirectly, beneficially or legally, of at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a person or entity in a particular jurisdiction) of such Party or other person or entity, as applicable, or such other comparable ownership interest with respect to any person or entity that is not a corporation; or (b) the power, direct or indirect, whether through ownership of voting securities or partnership or other ownership interests, by contract or otherwise of more than fifty percent (50%), to direct the management and policies of a Party or such other person or entity, as applicable. Notwithstanding the foregoing, "Affiliate" shall not include entities engaged in generics or biosimilar business to the extent they do not use or access Data, Know-How or other intellectual property licensed hereunder to conduct their generics or biosimilar business; such entities shall be considered Third Parties for purposes of this Agreement.

1.17 "*Agreed Percentage*" means, with respect to the Lead Product or any CoDev Collaboration Product, [\*\*\*] for Pieris and [\*\*\*] for Servier.

1.18 "*Agreement*" means this License and Collaboration Agreement together with the recitals and all exhibits, schedules and attachments hereto, which shall form an integral part of this Agreement.

1.19 "Alliance Manager" has the meaning set forth in Section 2.2.8.

1.20 "Anticalin" or "Anticalin protein" means, whether in nucleic acid or protein form, (a) any lipocalin mutein isolated from the Anticalin Libraries, or (b) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin mutein referred to in Section (a) of this definition, in each case, which binds and recognizes a specific target. For the sake of this Section, mutein shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

1.21 *"Anticalin Affinity Maturation"* means the process of engineering for an Anticalin protein to enhance its developability profile, such as increasing binding activities and specificity by introducing, e.g., one or more amino acid mutations.

1.22 "Anticalin Building Block" means an Anticalin protein used in a Product.

1.23 "*Anticalin Characterization*" means the assessment of [\*\*\*] and/or the evaluation of [\*\*\*] of Anticalin proteins and/or fusion proteins that include one or more Anticalin proteins.

1.24 *"Anticalin Expression*" means the heterologous expression of an Anticalin protein in a host cell.

4

1.25 *"Anticalin Fusion Technology"* means the process of fusing one or more Anticalin proteins to an immunoglobulin or fragment thereof to create bispecific, [\*\*\*] fusion proteins.

1.26 "Anticalin Libraries" means any phage display library based on (a) [\*\*\*] (Uniprot [\*\*\*]) or (b) [\*\*\*] (Uniprot [\*\*\*]).

1.27 "Anticalin Selection" means the process of screening an Anticalin Library with a defined target through the process of phage display, within a solution, and physically separating the target, containing binding Anticalin proteins, from the solution containing non-binding Anticalin proteins.

1.28 "*Antibody*" means any monoclonal or polyclonal antibody, whether multiple or single chain, recombinant or naturally occurring, whole or fragment, and any variants, derivatives or constructs thereof, including but not limited to, antigen binding portions including Fab, Fab', F(ab')2, Fv, dAb and CDR fragments, single chain antibodies (scFv), chimeric antibodies, diabodies and polypeptides (including any humanized versions thereof) that contain at least a portion of an immunoglobulin that is sufficient to bind selectively to a specific antigen or also named target. For the avoidance of doubt, an Antibody Building Block is an Antibody.

1.29 "Antibody Building Block" means an Antibody used in a Product.

- 1.30 "Arbitration" has the meaning set forth in Section 13.3.1.
- 1.31 "Arbitration Request" has the meaning set forth in Section 13.3.1.
- 1.32 "Audited Party" has the meaning set forth in Section 4.4.1.
- 1.33 "Auditing Party" has the meaning set forth in Section 4.4.1.
- 1.34 "Authorized Recipients" has the meaning set forth in Section 8.2.
- 1.35 "Beneficiary" has the meaning set forth in Section 2.1.5.(a).

1.36 "*Biological License Application*" or "*BLA*" means a Biological License Application in the United States as described in Section 351(a) of the United States Public Health Service Act (PHS Act), or an abbreviated Biological License Application as described in Section 351(k) of the PHS Act.

1.37 "*Biosimilar*" means, with respect to a given Product in a given country of the Servier Territory, any biological product on the market in such country that is approved (a) by the applicable Competent Authority in such country under the biosimilarity standard set forth in the United States under 42 U.S.C. §§ 262(i)(2) and (k), or any similar standard under its foreign equivalent applicable Law, on a country-by-country basis where such Product is marketed, provided that such applicable Law exists; and (b) in reliance in whole or in part, on a prior Marketing Approval (or on

5

any safety or efficacy data submitted in support of such prior Marketing Approval) of such Product. For countries or jurisdictions where no explicit biosimilar regulations exist, Biosimilar includes products which have been deemed to be a Biosimilar or otherwise deemed interchangeable by a Competent Authority in another country or jurisdiction. Any product or component thereof (including any Product or component thereof) licensed, marketed, sold, manufactured, or produced by or on behalf of a Party, its Affiliates or Sublicensees (to the extent such Sublicensee commercializes a Biosimilar in reliance on or access to the Data, Patents and Know-How licensed under this Agreement) will not constitute a Biosimilar.

1.38 *"Bispecific Product"* means a biologic entity which is the result of the fusion of different Building Blocks and which recognizes two (2) different targets. For clarity, a Bispecific Product can contain one (1) or more Antibody Building Block(s) and one (1) or more Anticalin Building Block(s) but can also be made of more than one (1) Anticalin Building Block(s), provided that the resulting Bispecific Product recognizes two (2) different targets.

1.39 "*Building Block*" means, individually, each of the Antibodies and each of the Anticalin proteins used in a Product. A Building Block can be either an Antibody Building Block or an Anticalin Building Block.

1.40 "Building Block IP" means the Intellectual Property Rights and Know-How Covering only each Building Block individually, but excludes the Product Specific IP, the Pieris Platform IP and the Pieris Platform Improvement IP.

1.41 "Business Day" means a day that is not a Saturday, Sunday or a day on which banking institutions in Paris, France or Munich, Germany, are authorized by applicable Law to remain closed.

1.42 "*Calendar Quarter*" means each three (3) consecutive calendar months ending on each March 31, June 30, September 30 and December 31.

1.43 "Calendar Year" means any period of time commencing on January 1 and ending on the next December 31.

1.44 "CDR" means complementarity determining region based on the IMGT (ImMunoGeneTics) method.

1.45 "*Change of Control*" means with respect to a Party, (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving such Party as a result of which either (1) the stockholders of such Party immediately preceding such transaction hold less than 50% of the outstanding shares, or less than 50% of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such

6

transaction owns the then-outstanding securities of such Party or all or substantially all of such Party's assets, including such Party's assets related to the Products, either directly or through one or more subsidiaries), or (2) any single Third Party person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a "Group") holds 50% or more of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of such Party or all or substantially all of such Party's assets either directly or through one or more subsidiaries); or (b) the direct or indirect acquisition (including by means of a tender offer or an exchange offer) by any Third Party person or Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect), or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, or found of a transaction solely to change the domicile of a Party shall not constitute a Change of Control as long as there is no change of direct or indirect shareholding.

1.46 "*Claim*" means any charge, complaint, action, suit, proceeding, hearing, investigation, claim or demand, including without limitation any investigation by a Government Authority.

1.47 "Claim Notice" has the meaning set forth in Section 11.3.1.

1.48 *"Clinical Development Costs*" means, unless otherwise provided in writing between the Parties, costs incurred in connection with Clinical Studies, whether such Clinical Studies are conducted by Servier or by Pieris, and determined in accordance with a cost per patient methodology using study drivers defined by both Parties or alternative methodologies agreed by the Parties. These costs per patient exclude CMC, translational activities and transversal activities (finance, human resources, project and alliance management).

1.49 "*Clinical Studies*" means research studies in humans that are (a) conducted in accordance with international ethical and scientific quality standards for designing, conducting, recording and reporting research studies involving investigational medicinal products for human use and that involve the participation of human subjects, which standards are established through Laws, and (b) designed to generate clinical data and results regarding a biological molecule in support of Marketing Approval, including any translational research studies. Clinical Studies include, but are not limited to, Phase 1 Clinical Study(ies), any Phase 2 (2a and/or 2b) Clinical Study(ies), or any Pivotal Clinical Study(ies).

1.50 "*CMC Costs*" means all Out-of-Pocket Cost incurred by Pieris for manufacturing the Lead Product pursuant to <u>Section</u> 2.4.2.(a) (or Collaboration

7

Product as applicable) as well as reasonable FTE Costs for managing the CMOs (with no premium or markup) in accordance with the applicable Joint Development Plan or Collaboration Plan and Joint Development Budget or Collaboration Budget.

1.51 "CMOs" has the meaning set forth in Section 2.4.2.(a).

1.52 "CMO Supply Agreement" has the meaning set forth in Section 2.4.2.(b)(i)2.

1.53 "Co-Chair" has the meaning set forth in Section 2.2.5.(b).

1.54 "CoDev Collaboration Product" has the meaning set forth in Section 3.1.4.(a).

1.55 "CoDev Collaboration Product Royalties" has the meaning set forth in Section 3.6.4.(b).

1.56 "Collaboration Budget" has the meaning set forth in Section 3.1.6.(a)(i).

1.57 "*Collaboration Effective Date*" means the Initial Collaboration Effective Date or Additional Collaboration Effective Date, as applicable.

1.58 "Collaboration Plan" has the meaning set forth in Section 3.1.2.(a).

1.59 "Collaboration Products" means the Initial Collaboration Products and the Additional Collaboration Products.

1.60 "Collaboration Renewal Development Funds" has the meaning set forth in Section 3.1.6.(a)(i).

1.61 *"Collaboration Renewal Term*" means the Initial Research Collaboration Renewal Term or the Additional Research Collaboration Renewal Term, as applicable.

1.62 "*Collaboration Term*" means the Initial Research Collaboration Term together with any Additional Research Collaboration Term, as applicable.

1.63 "Combination Product" has the meaning set forth in Section 1.152.

1.64 "*Commercialization*" means any and all activities of obtaining pricing and reimbursement strategy, marketing, promoting, distributing, importing, exporting, offering for sale, having sold, selling or conducting any other commercial exploitation activities relating to a Product. For clarity, "Commercialize" has a correlative meaning.

1.65 *"Commercially Reasonable Efforts"* means such level of effort and expenditure of resources required to carry out such obligation in a sustained manner consistent with the efforts and resources of a typical pharmaceutical company of a

8

similar size and with similar resources as Servier or Pieris together with their respective Affiliates, as applicable, typically devotes at the same stage of development or commercialization, as applicable, for its own internally developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life without regard to any payments owed under this Agreement. For clarity, the Parties understand that such product potential may change from time to time, based upon changing scientific, business and marketing and return on investment considerations.

1.66 "Committee" has the meaning set forth in Section 2.2.5.(a).

1.67 "*Compassionate Use*" means the use of a Product as an investigational drug (prior to Marketing Approval) in accordance with applicable Law outside of a Clinical Study to treat a patient with a serious or life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

1.68 "Competent Authority" means any regulatory agency, department, bureau, commission, council or other governmental entity of (a) any country, territory, national, federal, state, provincial, county, city or other political subdivision government, including the FDA, or (b) any supranational body (including the EMA), in any applicable jurisdiction in the world, involved in the granting of Regulatory Approval.

1.69 "*Competing Product*" means any bispecific protein (or to the extent [\*\*\*] is included in the collaboration hereunder, [\*\*\*]) that binds to and modulates the same therapeutically relevant targets (both in terms of identity as well as number, i.e. a bispecific protein binding and modulating the same two targets (and to the extent [\*\*\*] is included in the collaboration hereunder, [\*\*\*] and [\*\*\*]) as the Lead Product or a Collaboration Product, but excluding products using modalities other than bispecific proteins, such as (without limitation) CAR-T cells, antisense RNA, small molecules, or gene therapy. For purposes of this Agreement, the term "therapeutically relevant" means that the modulation of a given target is reasonably believed to be responsible, in whole or in part, for a specific aspect of the safety or efficacy of such product and would not, for example, include [\*\*\*] solely to [\*\*\*] or [\*\*\*], such as [\*\*\*]. For avoidance of doubt, no Product shall be a "Competing Product" with respect to any other Product. Further, for avoidance of doubt, if the Parties are developing a bispecific Product, [\*\*\*] does not constitute a Competing Product with respect to such Product so long as [\*\*\*].

1.70 "Competing Infringement" has the meaning set forth in Section 7.5.2.

1.71 "Concerned Party" has the meaning set forth in Section 6.2.2.

1.72 "Confidential Information" means any and all Know-How, information and Data of a confidential nature, whether financial, business, legal, technical or non-technical, whether in oral, written, electronic or other form, including information and

data related to a Product, a Party, or any concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement, that is disclosed, supplied or otherwise made available by or on behalf of one Party or any of its Affiliates or Sublicensees ("*Disclosing Party*") to the other Party or any of its Affiliates or Sublicensees ("*Receiving Party*") in connection with this Agreement. All Confidential Information disclosed by a Party pursuant to the Confidential Agreement between the Parties dated [\*\*\*] (the "*Prior CDA*") shall be deemed to be Confidential Information of such Party pursuant to this Agreement (with the mutual understanding and agreement that any use and disclosure thereof that is authorized under, and consistent with, <u>ARTICLE 8</u> shall not be restricted by, or be deemed a violation of, such Prior CDA).

1.73 "Consideration Period" has the meaning set forth in Section 3.1.4.

1.74 "Control", "Controlled" or "Controlling" means, with respect to a subject item (including any Intellectual Property Right, Know-How, Data, Regulatory Approvals or Regulatory Materials) ("Subject Item"), the possession (whether arising by ownership, pursuant to a license or sublicense or otherwise, other than pursuant to this Agreement) by a Party of the ability of such Party or its Affiliate to grant a license, sublicense or access to the other Party with respect to such Subject Item, as provided in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party (and subject to Section 4.1.2 and Section 4.1.3), in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license, sublicense or access. Notwithstanding anything to the contrary hereunder, the Pieris Platform IP and Pieris Platform Improvement IP will not be deemed to be "Controlled" by Pieris or its Affiliates for purposes of this Agreement.

1.75 "*Copyrights*" means all copyrights, and all right, title and interests in all copyrights, copyright registrations and applications for copyright registration, certificates of copyright and copyrighted rights and interests throughout the world, and all right, title and interest in related applications and registrations throughout the world.

1.76 "*Cover*", "*Coverd*" or "*Covering*" means, with respect to the applicable invention, discovery, process or product (including a Product), as appropriate, (a) a Patent Right, that, in the absence of a (sub)license under, or ownership of, such Patent Right, the Development, Manufacture or Commercialization of such invention, discovery, process or product (including making, using, offering for sale, selling or importing thereof), as appropriate, with respect to a given country, would infringe a Valid Claim of such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe any then-pending Valid Claim in such Patent Right if it were to issue with such claim), or (b) any Know-How, that, in the absence of a (sub)license under, or ownership of, such Know-How, the Development, Manufacture or Commercialization (including making, using, offering for sale, selling or importing thereof) of such invention, discovery, process or product incorporates, embodies or otherwise makes use of such Know-How.

10

#### 1.77 "Damages" has the meaning set forth in Section 11.1.

1.78 "*Data*" means any and all non-aggregated and aggregated research, pharmacology, pre-clinical, clinical, commercial, marketing, process development, manufacturing and other data or information, including investigator brochures and reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety data, in each case generated from, or related to, Clinical Studies or non-clinical studies, research or testing specifically related or directed to a Product. For the avoidance of doubt, Data shall be deemed Confidential Information of the Disclosing Party for the purposes of the Agreement subject to <u>ARTICLE 8</u> of this Agreement.

1.79 "Declined Option Collaboration Product" has the meaning set forth in Section 3.1.4.(b)(ii).

1.80 "Defending Party" has the meaning set forth in Section 7.5.3.(a).

1.81 "Development" means with respect to a Product, all research and all pre-clinical, non-clinical and clinical research and development activities performed to obtain and maintain the Marketing Approval for the relevant Product, including without limitation: test method development and stability testing, assay development, Translational Research, toxicology, pharmacology, formulation, quality assurance, quality development, statistical analysis, CMC process development and scale-up, pharmacokinetic studies, data collection and management, Clinical Studies (including research to design Clinical Studies and specifically excluding activities directed to obtaining pricing and reimbursement approvals), regulatory affairs (including submission of Data or other materials to a Competent Authority to obtain, maintain and/or expand Marketing Approval of a Product), project management, drug safety surveillance activities related to Clinical Studies, validation of methods and tests. For clarity, "Develop" and "Developing" have a correlative meaning.

1.82 "Development Data" has the meaning set forth in Section 2.3.4.(a).

1.83 "Disclosing Party" has the meaning set forth in Section 1.72.

1.84 "Dispute" has the meaning set forth in Section 13.3.1.

1.85 "Divest" or "Divestiture" has the meaning set forth in Section 6.2.2.(f)(i).

1.86 "*DMF*" means a drug master file and all equivalents, and related proprietary dossiers, in any country or jurisdiction for a Product submitted or to be submitted by a Party to Competent Authorities.

1.87 "DOCP Election Notice" has the meaning set forth in Section 3.1.4.(b)(ii).

11

- 1.88 "Drop Date" has the meaning set forth in Section 5.2.1.(b).
- 1.89 "Dropped Product" has the meaning set forth in Section 5.2.1.
- 1.90 "Dropped Product Notice" has the meaning set forth in Section 5.2.1.(a).
- 1.91 "Dropped Product Notice Period" has the meaning set forth in Section 5.2.1.(a).
- 1.92 "Dropping Party" has the meaning set forth in Section 5.2.1.(b).
- 1.93 "*Effective Date*" has the meaning set forth in the preamble.
- 1.94 "EMA" means the European Medicines Agency or any successor agency thereto.
- 1.95 [\*\*\*] means [\*\*\*].
- 1.96 "*EUR*" or "*€*" means Euros.

1.97 "*European Union*" or "*EU*" means the member states of the European Union as of the Effective Date (including for the avoidance of doubt, the United Kingdom), and such other countries as may become part of the European Union after the Effective Date. For clarity, to the extent the United Kingdom and/or any other member state of the European Union would not anymore be a member of the European Union after the Effective Date, it shall still be included in this definition of EU for the purposes of this Agreement.

1.98 "*Executive Officer*" means the Chief Executive Officer of Pieris and the Vice President of Research and Development or the Vice President of Business Development & Licensing of Servier, or their duly authorized respective designees with equivalent decision-making authority with respect to matters under this Agreement.

- 1.99 "Existing Pieris Patent Rights" has the meaning set forth in Section 10.2.1.(c).
- 1.100 "Existing Servier Patent Rights" has the meaning set forth in Section 10.3.1.(b).

1.101 "FDA" means the United States Food and Drug Administration or any successor entity thereto.

1.102 "*Field*" means, (a) with regard to the Lead Product, any therapeutic, palliative, prophylactic and diagnostic use in oncology and (b) with regard to a CoDev Collaboration Product and any Servier WW Collaboration Product, any therapeutic, palliative, prophylactic and diagnostic use for any human disease.

12

1.103 "Filing Party" has the meaning set forth in Section 2.1.5.(a).

1.104 *"First Commercial Sale"* means the first sale to a Third Party of a Product by or under the authority of Servier or its Affiliates or Sublicensees, in a country after receipt of the applicable Marketing Approval, as desirable in such country, from the Competent Authorities in that country. For the avoidance of doubt, Compassionate Use shall not be considered a First Commercial Sale.

1.105 "FTC" has the meaning set forth in Section 10.4.4.

1.106 *"FTE*" means full-time equivalent person-year of work performing activities hereunder. For clarity, indirect personnel (including support functions such as legal or business development) shall not constitute FTEs.

1.107 "*FTE Costs*" for a given period means the product of (a) the total FTEs (proportionately, on a per-FTE basis) dedicated by a Party or its Affiliates in the particular period to the direct performance of the activities allocated to such Party hereunder and (b) the FTE Rate.

1.108 *"FTE Rate"* means, unless otherwise agreed between the Parties, a rate per FTE equal to [\*\*\*] per annum (which may be prorated on a daily or hourly basis as necessary). The FTE Rate is "fully burdened" and will cover employee salaries, benefits, travel, and such facilities and equipment and other materials and services including ordinary laboratory and manufacturing consumables procured from distributors of relevant products as they may use.

1.109 "Global Branding Strategy" has the meaning set forth in Section 2.5.2.

1.110 "Global Commercialization Strategy" has the meaning set forth in Section 2.5.1.

1.111 "*GLP Tox Study*" means, with respect to a Product, a study conducted in a species using applicable regulatory good laboratory practices for the purposes of assessing the safety and the onset, severity, and duration of toxic effects and their dose dependency with the goal of establishing a profile required for an IND/IMPD. For the avoidance of doubt, preliminary toxicology studies are not regarded as a GLP Tox Study.

1.112 *"Government Authority"* means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other government instrumentality of (a) any country, territory, nation, state, province, county, city or other political subdivision thereof or (b) any supranational body, including any Competent Authority.

1.113 "Health Authority Communication" means any communication from any Competent Authority that concerns significant issues, including any of the

13

following: key product quality attributes (e.g., purity), safety findings affecting the platform (e.g., serious adverse events, emerging safety signals), clinical or non-clinical findings affecting patient safety, or lack of efficacy.

1.114 "HSR" has the meaning set forth in Section 10.4.4.

1.115 "*IND/IMPD*" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, (b) the Investigational Medicinal Product Dossier in the European Territory, or (c) the equivalent application to the applicable Competent Authority in any other regulatory jurisdiction, and any amendments to the foregoing (a), (b) or (c), in each case, the filing of which is necessary to initiate or conduct clinical testing of an investigational drug or biological product in humans in such jurisdiction.

- 1.116 "IND/IMPD Submission" means the filing of an IND/IMPD.
- 1.117 "Indemnified Party" has the meaning set forth in Section 11.3.1.
- 1.118 "Indemnifying Party" has the meaning set forth in Section 11.3.1.

1.119 "*Indication*" means a distinct type of disease or medical condition in humans to which a Product is directed and eventually approved. To distinguish one Indication from another Indication, the two Indications have to be (a) listed in two different blocks of the ICD-10 (chapter II, Neoplasms, version 2016) (as a way of example, any neoplasm under C15 is in a different block from any neoplasm under block C16, whereas C15.0 and C15.1 belong to the same block) and (b) developed under one or more separate Clinical Studies. Notwithstanding the foregoing, [\*\*\*] and [\*\*\*] shall be deemed to be two distinct Indications and [\*\*\*] shall be considered as one Indication.

1.120 "Infringement Action" has the meaning set forth in Section 7.5.4.(a).

- 1.121 "Initial Collaboration Effective Date" means the Effective Date.
- 1.122 "Initial Collaboration Products" has the meaning set forth in Section 3.1.1.(b).
- 1.123 "Initial Research Collaboration" has the meaning set forth in <u>Section 3.1.1</u>.

1.124 *"Initial Research Collaboration Term*" means that period of time commencing upon the Effective Date and continuing for three (3) years thereafter.

1.125 "Initial Research Collaboration Renewal Term" has the meaning set forth in Section 3.1.1.(a).

14

1.126 "Insolvent Party" has the meaning set forth in Section 12.3.5.

1.127 "Intellectual Property Rights" means, collectively, Patent Rights, Copyrights, Trademarks, designs, domain names, moral rights and all other intellectual property and proprietary rights.

- 1.128 "Joint Development Budget" has the meaning set forth in Section 2.3.2.(a).
- 1.129 "Joint Development Committee" or "JDC" has the meaning set forth in Section 2.2.3.
- 1.130 "Joint Development Plan" has the meaning set forth in Section 2.3.1.(a).
- 1.131 "Joint Executive Committee" or "JEC" has the meaning set forth in Section 2.2.1.
- 1.132 "Joint IP" means collectively, Joint Know-How and Joint Patents, including all Intellectual Property Rights therein.
- 1.133 "Joint Intellectual Property Committee" or "JIPC" has the meaning set forth in Section 2.2.4.

1.134 "*Joint Know-How*" means all Product Specific Know-How or other Know How Controlled by either Party created, invented or generated by employees, agents, or independent contractors of a Party or both Parties or its/their Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under the Joint Development Plan or the Collaboration Plan pursuant to this Agreement but excluding any Know-How specifically related to (a) any Servier Building Block or (b) any Pieris Building Block, which shall be solely owned by the applicable Party, regardless of whether such Know-How would otherwise meet the definition of "Joint Know-How" hereunder. For avoidance of doubt, Joint Know-How also specifically excludes Know-How within the Pieris Platform IP or the Pieris Platform Improvement IP or related to the Pieris Platform Technology.

1.135 "*Joint Patent*" means all Product Specific Patents or other Patents Controlled by either Party that claim an invention created, invented or generated by employees, agents, or independent contractors of a Party or both Parties or its/their Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under the Joint Development Plan or a Collaboration Plan pursuant to this Agreement but excluding any Patent that claims any Pieris Platform IP, Pieris Platform Improvement IP, Servier Building Block or any Pieris Building Block, regardless of whether such Patent would otherwise meet the definition of a Joint Patent hereunder. Notwithstanding the foregoing, the Product Specific Patents related to the Lead Product filed during or prior to January 2017 shall be solely owned by Pieris, and shall not constitute Joint Patents hereunder.

15

1.136 "Joint Research Committee" or "JRC" has the meaning set forth in Section 3.3.1.

1.137 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.2.2.

1.138 *"Know-How*" means any and all ideas, concepts, designs, technical information, techniques, Data, database rights, discoveries, inventions, practices, methods, procedures, processes, methods, algorithm, knowledge, skill, experience, test data and any other information or technology, whether in written, electronic, graphic or any other form, including pharmaceutical, chemical, biological and biochemical compositions, formulations, assays, APIs, molecules, samples, cell lines, journals and laboratory notebooks.

1.139 "*Law*" means any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any applicable Government Authority, including any rules, regulations, guidelines, directives or other requirements of applicable Government Authorities, including good clinical practices, good laboratory practices and good manufacturing practices, as well as all anti-bribery or anti-corruption laws, as applicable.

1.140 "*Lead Product*" means a Bispecific Product directed against PD-1 and [\*\*\*]. The Lead Product contains at least [\*\*\*] Anticalin Building Blocks directed against [\*\*\*] and a PD-1 Antibody Building Block, as will be agreed between the Parties. The Lead Product may also be referred to as "*PRS-332*".

1.141 *"Lead Product Drug Candidate Nomination"* or *"Lead Product DCN"* means the provision by Pieris of Required Data as set forth in <u>Section 2.6.2</u> and achievement of the criteria set forth in <u>Exhibit 1.141</u>.

1.142 "Lead Product Project" has the meaning set forth in the recitals.

1.143 "Lead Product Royalties" has the meaning set forth in Section 2.6.6.

1.144 "Lead Product Upfront Fee" has the meaning set forth in Section 2.6.1.

1.145 "Licensor" has the meaning set forth in Section 5.1.3.(a).

1.146 "MAA" means a Marketing Authorization Application, in relation to any Product, filed or to be filed with the EMA (or equivalent national agency), for authorization to place a medicinal product on the market in the European Union (or any other territory).

16

#### 1.147 "Major Market Country" means [\*\*\*].

1.148 "*Manufacture*" means, with respect to a Product, all activities related to the manufacture of the Products, including, but not limited to, manufacturing supplies for Development or Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, shipment, import and export as needed, improvement of production, improvement of manufacturing processes, and regulatory activities related to any of the foregoing. For clarity, "Manufacturing" has a correlative meaning.

1.149 "*Marketing Approval*" means all approvals, licenses, registrations or authorizations of the Competent Authorities in a country, necessary for the commercial marketing and sale of the Product in such country, including the approval of a MAA or a BLA.

1.150 "Material Adverse Effect" has the meaning set forth in Section 2.2.6.(d).

1.151 "Medical Journals" has the meaning set forth in Section 9.2.1.

1.152 "*Net Sales*" means, in the case of sales by or for the benefit of Servier, its Affiliates, and its Sublicensees (in each case, "*Seller*") in the Territory to a Third Party, the gross amount of monies invoiced by Seller with respect to the Products, less the following deductions ("*Permitted Deductions*"):

(a) trade, cash, promotional and quantity discounts to the extent actually given;

(b) taxes on sales (such as excise, sales or use taxes or value added tax), but excluding any taxes on Seller's income;

(c) customary freight, insurance, packing costs and other transportation charges added to the sales price that are incurred in delivering the Product;

 (d) amounts repaid or credits taken by reason of rejections, defects or returns or because of retroactive price reductions, or due to recalls or applicable Laws requiring rebates;

(e) free good, rebates taken by or distribution fees paid to distributors, and charge-backs;

(f) customs duties actually paid by Seller on import into the country of sale to the extent invoiced and not otherwise reimbursed;

17

(g) rebates and/or discounts on sales of Products given to health insurance and other types of payers in any given country of the Servier Territory due to specific agreement ("claw-back" type of agreements) with respect to the Products;

(h) the actual amount of any write-offs for bad debt in accordance with the standard practices of Seller for writing off uncollectible amounts consistently applied; provided with respect to such write-off that an amount subsequently recovered or reversed with respect to such write-off will be treated as Net Sales in the quarter in which it is recovered or reversed; and

(i) any other specifically identifiable amounts included in gross amounts invoiced for the Products, to the extent such amounts are customary deductions from net sales calculations in accordance with IFRS as consistently applied by Servier, its Affiliates, and its Sublicensees for reporting their respective net sales.

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in clauses (a)-(i) above, such item may not be deducted more than once.

"*Net Sales*" shall not include any consideration received with respect to a sale, use or other disposition of any Product in a country for purposes of conducting Clinical Studies in the course of Development of the Product in accordance with this Agreement or as samples (reasonable in number) or for Compassionate Use, in each case provided that Seller does not receive consideration of monetary value for such Products. Notwithstanding the foregoing, the amounts invoiced by Servier, its Affiliates, or their Sublicensees for the sale of Product among Servier, its Affiliates or their respective Sublicensees for resale shall not be included in the computation of Net Sales hereunder (except where such Affiliates or Sublicensees are the end users) and Net Sales shall be the gross invoice or contract price charged to the Third Party customer for that Product in an arms' length transaction, less the Permitted Deductions. Net Sales calculations shall be determined in accordance with Accounting Standards consistently applied throughout the organization and across all products of the entity whose sales of Products are giving rise to Net Sales. In the case of any sale or other transfer for value, such as barter or counter-trade, of a Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Product in the country of sale or transfer, as determined in accordance with Accounting Standards consistently applied (as contemplated above).

In the case where a Product is sold as part of a Combination Product in a country in the Territory, Net Sales for the Product included in such Combination Product in such country shall be calculated as follows:

(i) if the Product is sold separately in such country and the other active ingredient or ingredients in the Combination Product are sold separately in such country, Net Sales for the Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B),

18

where A is the invoice price of the Product when sold separately in such country and B is the total invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country;

(ii) if the Product is sold separately in such country but the other active ingredient or ingredients in the Combination Product are not sold separately in such country, Net Sales for the Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the invoice price of the Product when sold separately in such country and D is the invoice price of the Combination Product in such country;

(iii) if the Product is not sold separately in such country but the other active ingredient or ingredients in the Combinations Product are sold separately in such country, Net Sales for the Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction 1 - (B/D), where B is the invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country and D is the invoice price of the Combination Product in such country; or

(iv) if neither the Product nor the other active ingredient or ingredients in the Combination Product are sold separately in such country, the Parties shall determine Net Sales for the Product in such Combination Product by mutual agreement based on the relative contribution of the Product and each other active ingredient to the Combination Product, and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

For purposes of this <u>Section 1.152</u>, "*Combination Product*" means a product that includes at least one active ingredient other than a Product, when a single sale or reimbursement price is set for such Combination Product.

1.153 *"Non-Clinical Development"* shall mean non-clinical activities conducted in relation to a Product which has obtained an IND/IMPD.

1.154 *"Non-Clinical Development Costs"* shall mean the Out-of-Pocket Costs, as well as FTE Costs, associated with Non-Clinical Development activities.

1.155 "Non-Proposing Party" has the meaning set forth in Section 2.3.3.

1.156 "Non-Sublicensing Party" has the meaning set forth in Section 5.1.3.(b)(i).

1.157 "Objection Period" has the meaning set forth in Section 2.3.3.(b).

1.158 "Opt-In Notice" has the meaning set forth in Section 3.1.4.

19

1.159 "**Out-of-Pocket Costs**" means all direct project expenses paid or payable to Third Parties after the Effective Date, which are specifically identifiable and incurred for services or materials provided by them directly in their performance of the Development or Manufacture of the Products in the Servier Territory or Pieris Territory, as applicable; such expenses to have been recorded as income statement items in accordance with Accounting Standards and for the avoidance of doubt, not including pre-paid amounts (until expensed in accordance with Accounting Standards). Notwithstanding the foregoing, Out-of-Pocket Costs do not include Clinical Development Costs. For clarity, Out-of-Pocket Costs do not include capital expenditures (unless mutually agreed by the Parties), travel expenses or items intended to be covered under the definition of FTE Costs.

1.160 "*Partnering Agreement*" means with respect to any Product, an agreement with a Third Party to license or sublicense, transfer, assign or sell (in each case, including an option to do so) all or part of its rights and obligations to Develop and to Commercialize such Product.

- 1.161 "Party" or "Parties" has the meaning set forth in the preamble.
- 1.162 "Party Supply Agreement" has the meaning set forth in Section 2.4.2.(b)(i)1.

1.163 "**Patent Right**" or "**Patent**" means any and all patent rights and all right, title and interest in all patent applications and patents that issue from them, all letters patent or equivalent rights and applications in each case to the extent the same has not been held, by a court of competent jurisdiction, to be invalid or unenforceable in a decision from which no appeal can be taken or from which no appeal was taken within the time permitted for appeal. Patent Rights include any extension, registration, confirmation, reissue, continuation, supplementary protection certificate, divisional, continuation-in-part, re-examination or renewal thereof or foreign counterparts of any of the foregoing.

- 1.164 "Payee Party" has the meaning set forth in Section 4.3.3.
- 1.165 "Payor Party" has the meaning set forth in Section 4.3.3.
- 1.166 *"[\*\*\*]*" or *"[\*\*\*]*" means [\*\*\*].
- 1.167 "Permitted Deductions" has the meaning set forth in <u>Section 1.152</u>.
- 1.168 "Pharmacovigilance Agreement" has the meaning set forth in Section 2.3.7.(f).

20

1.169 "*Phase 1 Clinical Study*" means a clinical study of a product in human subjects which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, as described in 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).

1.170 "*Phase 1 Clinical Study Expansion Cohort*" means the expansion of a Phase 1 Clinical Study to include additional patient(s) following the selection of a dose during the dose escalation part of the Phase 1 Clinical Study (such as a maximum tolerated dose).

1.171 "*Phase 2 (2a and/or 2b) Clinical Study*", "*Phase 2a Clinical Study*" or "*Phase 2b Clinical Study*" means a clinical study of a product that is prospectively designed to establish the safety, dose ranging and efficacy of a product as further defined in 21 C.F.R. § 312.21(b) (or the non-United States equivalent thereof).

1.172 "Pieris" has the meaning set forth in the preamble.

1.173 "Pieris Background Agreements" means [\*\*\*].

1.174 "Pieris Building Block" means any Anticalin Building Block and any Antibody Building Block Controlled by Pieris.

1.175 "*Pieris Building Block IP*" means all Intellectual Property Rights and Know-How Covering any and all Anticalin Building Blocks and Antibody Building Blocks Controlled by Pieris.

1.176 "Pieris Co-Development Option" has the meaning set forth in Section 3.1.4.

1.177 "*Pieris Designated CoDev Collaboration Products*" means, (a) with respect to the Initial Research Collaboration, the two (2) Collaboration Products set forth in Part 1 of <u>Schedule 1.177</u>, and (b) with respect to the Additional Research Collaboration (as applicable), the one (1) Collaboration Product to be mutually agreed by the Parties in accordance with <u>Section 3.1.1.(c)</u> and set forth in Part 2 of <u>Schedule 1.177</u>.

1.178 "Pieris Indemnitees" has the meaning set forth in Section 11.2.

1.179 "*Pieris IP*" means any and all Pieris Patent Rights and the Pieris Know-How, including any Intellectual Property Rights therein, but excludes the Pieris Platform IP and Pieris Platform Improvement IP. For the avoidance of doubt, Pieris IP shall include Pieris Building Block IP and any Product Specific IP that is Controlled by Pieris as of the Effective Date and thereafter during the Term and Pieris' interest in the Joint IP.

21

1.180 "*Pieris Know-How*" means all Know-How that is Controlled by Pieris as of the Effective Date and thereafter during the Term other than pursuant to the licenses granted by Servier under this Agreement and is (a) used in connection with or otherwise Covers the Development, Manufacture, or Commercialization of the Products or (b) reasonably necessary for the Development, Manufacture, or Commercialization of a Product, but excludes the Pieris Platform IP and Pieris Platform Improvement IP. Pieris Know-How shall include Pieris' interest in Joint Know-How.

1.181 "Pieris Partner" has the meaning set forth in Section 5.1.1.(a).

1.182 "*Pieris Patent Rights*" means any Patent Rights that are Controlled by Pieris as of the Effective Date and thereafter during the Term, and that Cover or are necessary for the Development, Manufacture or Commercialization of the Products pursuant to the terms of this Agreement, but excludes the Pieris Platform IP and Pieris Platform Improvement IP. Pieris Patent Rights shall include Pieris' interest in Joint Patents. The Pieris Patent Rights existing as of the Effective Date are set forth in <u>Schedule 1.182</u>.

1.183 "*Pieris Platform Improvement IP*" means any and all Know-How created, invented or generated by or on behalf of employees, agents, or independent contractors of either Party or their Affiliates (whether alone or jointly) in the course of performing activities pursuant to this Agreement that constitutes an improvement, modification or enhancement to, or derivative of, the Pieris Platform IP, including all Intellectual Property Rights therein.

1.184 "*Pieris Platform IP*" means (a) the Know-How Controlled by Pieris that is necessary or useful for the practice of the Pieris Platform Technology, and (b) those Patents Rights Controlled by Pieris directed to the Pieris Platform Technology as set forth in <u>Schedule 1.184</u>.

1.185 *"Pieris Platform Technology"* means Anticalin Libraries, Anticalin Selection, Anticalin Expression, Anticalin Characterization, Anticalin Fusion Technology, and Anticalin Affinity Maturation methods, all to the extent Controlled by Pieris.

1.186 "Pieris ROFN Notice" has the meaning set forth in Section 5.1.1.(b).

1.187 "Pieris ROFN Product" has the meaning set forth in Section 5.1.1.(a).

1.188 "Pieris ROFN Product Amendment" has the meaning set forth in Section 5.1.1.(b).

1.189 "*Pieris Territory*" means, with respect to the Lead Product and any CoDev Collaboration Product, the United States of America.

22

1.190 "Pieris Territory Commercialization Plan" has the meaning set forth in Section 2.5.1.(b).

1.191 "Pieris' Contribution" has the meaning set forth in Section 4.1.3.(a).

1.192 "*Pivotal Clinical Study*" means a clinical study of a product that is designed to generate statistically significant evidence of the efficacy of a product for a particular Indication or use (as well as additional safety information) and that is intended to form the primary scientific support for filing a BLA to obtain Marketing Approval to market the product, (or any MAA for the non-United States equivalent thereof).

1.193 "*Platform Agreement*" means that certain non-exclusive license agreement to the Pieris Platform Technology entered into between Servier and Pieris on the date hereof. The Platform Agreement is set forth on <u>Exhibit 1.193</u> to this Agreement.

1.194 "Prior CDA" has the meaning set forth in Section 1.72.

1.195 "*Product*" means the Lead Product and any Collaboration Product, including CoDev Collaboration Product and Servier WW Collaboration Product, as applicable.

1.196 "*Product Specific IP*" means all Product Specific Patents and Product Specific Know-How, including all Intellectual Property Rights therein.

1.197 "*Product Specific Know-How*" means all Know-How that is Controlled by either Party or both Parties as of the Effective Date and thereafter during the Term and (a) that is used in connection with or otherwise Covers the Development, Manufacture, or Commercialization of a Product or (b) is reasonably necessary or useful for the Development, Manufacture, or Commercialization of a Product but excludes the Know-How specifically related to Building Block IP and Pieris Platform IP and Pieris Platform Improvement IP.

1.198 *"Product Specific Patents"* means any Patent Rights Controlled by either Party or both Parties as of the Effective Date and thereafter during the Term, that Cover the Development, Manufacture or Commercialization of any Product, but exclude the Building Block IP and Pieris Platform IP and Pieris Platform IP.

1.199 "Product Trademarks" has the meaning set forth in Section 7.6.1.

1.200 "Promotional Materials" has the meaning set forth in Section 2.5.2.

1.201 "Proposed Study(ies)" has the meaning set forth in Section 2.3.3.

23

1.202 "Proposing Party" has the meaning set forth in Section 2.3.3.

1.203 "PRS-332" has the meaning set forth in Section 1.140.

1.204 "*Raw Data*" has the meaning set forth in <u>Section 2.1.5.(d)</u>.

1.205 "Receiving Party" has the meaning set forth in Section 1.72.

1.206 "Reconciliation Report" has the meaning set forth in Section 4.2.2.(b).

1.207 "*Regulatory Approval*" means any and all approvals, licenses, registrations or authorizations by a Competent Authority necessary for the Development activities (including any IND/IMPD approval), Manufacturing activities or Commercialization activities (including, where applicable, Marketing Approval, pricing, labeling and reimbursement determinations or approvals).

1.208 "*Regulatory Exclusivity*" means any exclusive marketing rights or data exclusivity rights conferred by any applicable Competent Authority, other than an issued and unexpired Patent, including any regulatory data protection exclusivity (including, where applicable, pediatric exclusivity and/or orphan drug exclusivity) and/or any other exclusivity afforded by restrictions which prevent the granting by a Competent Authority of regulatory approval to market a Biosimilar.

1.209 "*Regulatory Materials*" means regulatory applications, submissions, dossiers, notifications, registrations, case report forms, trial master file, DMF, common technical documents, question and answers with Competent Authorities, Marketing Approvals or other filings or communications made to or with, or other approvals granted by, a Competent Authority that are necessary or reasonably desirable in order to Develop, Manufacture or Commercialize a Product in a particular country or regulatory jurisdiction.

1.210 "Required Data" has the meaning set forth in Section 2.6.2.

1.211 "Research Collaboration" means the Initial Research Collaboration or Additional Research Collaboration, as applicable.

1.212 "Responsible Party" has the meaning set forth in Section 7.5.5.

1.213 "*Royalties*" means, collectively, the Lead Product Royalties, the Servier WW Collaboration Product Royalties and the CoDev Collaboration Product Royalties.

1.214 *"Royalty Bearing Net Sales"* means on a country-by-country and Product-by-Product basis, the Net Sales generated during the Royalty Term for such Product in such country.

24

1.215 "*Royalty Term*" means, on a country-by-country basis and a Product-by-Product basis, the period commencing on the First Commercial Sale of the Product in a country and ending with respect to such Product in such country on the later of (a) ten (10) years thereafter in such country; (b) last to expire Regulatory Exclusivity relating to such Product; or (c) expiration of the last to expire Valid Claim of any Patent Right within the Pieris IP and Joint IP in each case, Covering such Product in such country [\*\*\*].

- 1.216 "Rules" has the meaning set forth in Section 13.3.1.
- 1.217 "Scientific Meeting" has the meaning set forth in Section 9.2.2.
- 1.218 "Scientific Paper" has the meaning set forth in Section 9.2.1.
- 1.219 "SEC" has the meaning set forth in Section 8.6.2.
- 1.220 "Seller" has the meaning set forth in Section 1.152.
- 1.221 "Sensitive Information" has the meaning set forth in Section 6.2.2.(f)(ii).
- 1.222 "Servier" has the meaning set forth in the preamble.
- 1.223 "Servier Background Contract" means that [\*\*\*].
- 1.224 "Servier Building Block" means any Antibody Building Block Controlled by Servier.

1.225 "Servier Building Block IP" means all Intellectual Property Rights and Know-How Covering any and all Antibody Building Blocks Controlled by Servier.

- 1.226 "Servier Collaboration Option" has the meaning set forth in Section 3.1.1.(c).
- 1.227 "Servier Collaboration Option Fee" has the meaning set forth in Section 3.6.1.(b).
- 1.228 "Servier Collaboration Option Period" has the meaning set forth in Section 3.1.1.(c).
- 1.229 "Servier Indemnitees" has the meaning set forth in Section 11.1.

1.230 "Servier IP" means any and all Servier Patent Rights and Servier Know-How, including any Intellectual Property Rights therein. For the avoidance of doubt, Servier IP shall include Servier Building Block IP and any Product Specific IP that is Controlled by Servier as of the Effective Date and thereafter during the Term and Servier's interest in the Joint IP.

25

1.231 "*Servier Know-How*" means all Know-How that is developed or Controlled by Servier as of the Effective Date and thereafter during the Term other than pursuant to the licenses granted by Pieris under this Agreement and is used in connection with or otherwise Covers the Development, Manufacture, or Commercialization of the Products. Servier Know-How shall include Servier's interest in Joint Know-How.

1.232 "Servier Opt-In Notice" has the meaning set forth in Section 3.1.1.(c).

1.233 "Servier Partner" has the meaning set forth in Section 5.1.2.(a).

1.234 "*Servier Patent Rights*" means any Patent Rights that are Controlled by Servier as of the Effective Date and thereafter during the Term, and that Cover or are necessary for the Development, Manufacture or Commercialization of the Products (including its composition, formulation, combination, product by process, or method of use, manufacture, preparation or administration) pursuant to the terms of this Agreement. Servier Patent Rights shall include Servier's interest in Joint Patents that meet the above requirements. The Servier Patent Rights existing as of the Effective Date are set forth in <u>Schedule 1.234</u>.

1.235 "Servier ROFN Notice" has the meaning set forth in Section 5.1.2.(b).

1.236 "Servier ROFN Product" has the meaning set forth in Section 5.1.2.(a).

1.237 "Servier ROFN Product Agreement" has the meaning set forth in Section 5.1.2.(b).

1.238 "Servier Territory" means (a) with respect to the Lead Product and any CoDev Collaboration Product, the entire world except for the United States and (b) with respect to a Servier WW Collaboration Product, the entire world.

1.239 "Servier Territory Commercialization Plan" has the meaning set forth in Section 2.5.1.(a).

1.240 "Servier WW Collaboration Product" has the meaning set forth in Section 3.1.4.(b)(i).

1.241 "Servier WW Collaboration Product Royalties" has the meaning set forth in Section 3.6.4.(a).

26

#### 1.242 "Servier's Contribution" has the meaning set forth in Section 4.1.3.(a).

1.243 "Shared Costs" means: (a) all Out-of-Pocket Costs (on a pass-through basis with no mark-up) for pre-clinical Development (including research) activities, (b) all Translational Research Costs, (c) all Clinical Development Costs, (d) Non-Clinical Development Costs, and (e) CMC Costs, and, in each case as such costs are incurred by the Parties or their Affiliates after the Effective Date in accordance with a Collaboration Plan and the corresponding Collaboration Budget, or the Joint Development Plan and the Joint Development Budget, as applicable. Shared Costs shall not include costs incurred by a Party in the performance of any Territory Specific Work or Unsponsored Work.

1.244 "Shared Cost Report" has the meaning set forth in Section 4.2.2.(a)

1.245 "*Start*" means, with respect to a given (a) Clinical Study, the first dosing of the first research subject with a Product in such Clinical Study, and (b) GLP Tox Study, the start date of the in-life phase of such GLP Tox Study.

1.246 "Subject Item" has the meaning set forth in Section 1.74.

1.247 "*Sublicensee*" means a Third Party which is a licensee or sublicensee of the Pieris IP or the rights granted to Servier or Pieris, as applicable, under this Agreement, in accordance with the terms and conditions of this Agreement. For sake of clarity, Sublicensees do not include (a) wholesalers, distributors or similar entities performing similar functions, even if such Third Party is granted a limited right to promote and resell a Product sold to it and (b) Affiliates of the Party that has been granted the license (i.e., Servier or Pieris, as applicable).

1.248 "Sublicensing Party" has the meaning set forth in Section 5.1.3.(b)(i).

1.249 "Term" has the meaning set forth in Section 12.1.

1.250 *"Territory*" means either the Servier Territory or the Pieris Territory, as applicable given the context of the use of the term.

1.251 *"Territory Specific Work"* means any Clinical Study or non-clinical study that is required only by Competent Authorities in any given jurisdiction (or group of jurisdictions) in order to obtain or maintain Regulatory Approval for the Product in such jurisdiction, and not by Competent Authorities in other jurisdictions (or group of jurisdictions).

1.252 "Third Party" means any person or entity other than Pieris, Servier and their respective Affiliates.

27

- 1.253 "Third Party Claim" has the meaning set forth in Section 11.1.
- 1.254 "Third Party IP Claim" has the meaning set forth in Section 7.5.1.
- 1.255 "Third Party License" has the meaning set forth in Section 4.1.2.(a).
- 1.256 "*f*\*\*\**f*" has the meaning set forth in <u>Section 5.1.2.(c)</u>.

1.257 *"Trademarks"* means all trademarks, service marks, trade names, rights in trade dress, logos, symbols, brand names and all trademark rights and interests throughout the world, and all right, title and interest in related applications and registrations throughout the world under common law, state law, federal law or laws of foreign countries.

1.258 "Transferring Party" has the meaning set forth in Section 3.2.5.(a).

1.259 "*Translational Research*" means all laboratory and clinical investigation performed before and during the clinical testing of a product aimed at defining patients that will benefit from treatment with the product (i.e. proof-of-concept preclinical studies; identification and validation of selection biomarkers) and the determination of biomarkers that will help follow the response to the treatment (identification and validation of response biomarkers).

1.260 *"Translational Research Costs"* shall mean the Out-of-Pocket Costs, as well as FTE Costs, associated with Translational Research.

#### 1.261 "Unsponsored Work" has the meaning set forth in Section 2.3.3.(b).

1.262 "Valid Claim" means (a) a claim of an issued and unexpired Patent Right, which claim has not been revoked or held invalid or unenforceable by a court or other government agency of competent jurisdiction by a determination or has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity suit or otherwise by a determination or (b) a claim of a pending Patent Right application that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling; provided, however, that Valid Claim will exclude any such pending claim in an application that has not been granted within [\*\*\*] years following the earliest priority filing date for such application. For purposes of the definition of Valid Claim, "determination" means a determination with respect to a Patent Right that would prevent a Party from enforcing or continuing to enforce such Patent Right. To the extent that any Patent Right is issued, restored or otherwise deemed valid and enforceable, then it once again shall be considered a Valid Claim as from the date of such issuance, restoration or determination.

28

- 1.263 "Withholding Taxes" has the meaning set forth in Section 4.3.3.
- 1.264 "Working Group" has the meaning set forth in Section 2.2.7.

#### **ARTICLE 2 LEAD PRODUCT PROJECT**

#### Section 2.1 Licenses.

#### 2.1.1 License Grants to Servier.

2.1.1.(a) <u>Development License</u>. Subject to the terms and conditions set forth herein, Pieris hereby grants to Servier a co-exclusive (with Pieris), sublicensable (subject to <u>Section 2.1.3</u> below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Pieris IP (i) to Develop and have Developed (subject to <u>Section 2.3.6</u>), the Lead Product in the Field anywhere in the Pieris Territory and the Servier Territory, including to perform Servier's obligations under the Joint Development Plan and to undertake Territory Specific Work and Unsponsored Work as permitted herein, and (ii) (a) to Manufacture, have Manufactured (subject to <u>Section 2.3.6</u>), the Lead Product anywhere in the Pieris Territory and the Servier Territory and the Servier Territory and the Pieris Territory, in each case (clause (a) and (b)), solely for such Development; provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this <u>Section 2.1.1.(a)</u> shall be non-exclusive.

2.1.1.(b) <u>Commercialization License</u>. Subject to the terms and conditions set forth herein during the Term, Pieris hereby grants to Servier a royalty-bearing, sublicensable (subject to <u>Section 2.1.3</u> below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Pieris IP (i) to Commercialize the Lead Product in the Field solely in the Servier Territory, the license granted in this clause (i) to be exclusive (even as to Pieris), and (ii) (a) to Manufacture, have Manufactured (subject to Section <u>2.3.6</u>), the Lead Product anywhere in the Pieris Territory and the Servier Territory, and (b) to import the Lead Product into the Servier Territory, in each case (clause (a) and (b)), solely for such Commercialization, the license granted in this clause (ii) to be a co-exclusive (with Pieris); provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this <u>Section 2.1.1.(b)</u> shall be non-exclusive.

#### 2.1.2 License Grants to Pieris.

2.1.2.(a) <u>Development License</u>. Subject to the terms and conditions set forth herein, Servier hereby grants to Pieris a co-exclusive (with Servier), sublicensable (subject to <u>Section 2.1.3</u> below), personal and non-transferable

29

(except as set forth in <u>Section 13.5</u>), right and license under the Servier IP (i) to Develop and have Developed (subject to <u>Section 2.3.6</u>), the Lead Product in the Field anywhere in the Pieris Territory and the Servier Territory, including to perform Pieris' obligations under the Joint Development Plan and to undertake Territory Specific Work and Unsponsored Work as permitted herein, and (ii) (a) to Manufacture, have Manufactured (subject to <u>Section 2.3.6</u>), the Lead Product anywhere in the Pieris Territory and the Servier Territory, and (b) to import the Lead Product into the Servier Territory and the Pieris Territory, in each case (clause (a) and (b)), solely for such Development; provided that with respect to any Servier Building Block IP within the Servier IP, the foregoing license under this <u>Section 2.1.2.(a)</u> shall be non-exclusive.

2.1.2.(b) <u>Commercialization License</u>. Subject to the terms and conditions set forth herein during the Term, Servier hereby grants to Pieris a royalty-free, sublicensable (subject to <u>Section 2.1.3</u> below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Servier IP (i) to Commercialize the Lead Product in the Field solely in the Pieris Territory, the license granted in this clause (i) to be exclusive (even as to Servier), and (ii) (a) to Manufacture, have Manufactured (subject to <u>Section 2.3.6</u>), the Lead Product anywhere in the Pieris Territory and the Servier Territory, and (b) to import the Lead Product into the Pieris Territory, in each case (clause (a) and (b)), solely for such Commercialization, the license granted in this clause (ii) to be co-exclusive (with Servier); provided that with respect to any Servier Building Block IP within the Servier IP, the foregoing license under this <u>Section 2.1.2.(b)</u> shall be non-exclusive.

2.1.3 <u>Sublicense</u>. Servier or Pieris may sublicense (through multiple tiers) all or part of the rights and licenses granted to them under this <u>Section 2.1</u> to an Affiliate or to a Third Party solely in accordance with the terms set forth in <u>Section 5.1.2</u> and <u>Section 5.1.3</u>.

## 2.1.4 Know-How Transfer.

2.1.4.(a) <u>Initial Transfer</u>. Within thirty (30) days of the Effective Date, Pieris shall make available to Servier the Pieris Know-How related to the Lead Product that has not been previously made available to Servier, including the items listed in <u>Exhibit 2.1.4.(a)</u>.

2.1.4.(b) <u>Ongoing Transfer</u>. Subject to <u>Section 3.3.4</u>, when applicable, on a continuing basis throughout the Term, (i) Pieris shall promptly make available to Servier all additional Pieris Know-How related to the Lead Product which comes into existence from time to time, including all information listed in <u>Exhibit 2.1.4.(b)</u> and all Data generated under the Joint Development Plan, Territory Specific Work or under any

30

Unsponsored Work in accordance with <u>Section 2.3.3</u>, and all Know-How within the Joint IP which comes into existence from time to time (other than the Know-How related to Manufacturing, which is covered by <u>Section 3.4</u>) and (ii) Servier shall promptly make available to Pieris all Servier Know-How related to the Lead Product which comes into existence from time to time, including all Data generated under to the Joint Development Plan, Territory Specific Work or under any Unsponsored Work in accordance with <u>Section 2.3.3</u>, and all Know-How within Joint IP which comes into existence from time to time (other than the Know-How related to Manufacturing, which is covered by <u>Section 3.4</u>). Any such documents, reports and data intended to be submitted to Competent Authorities shall be made available in a form and format acceptable by Competent Authorities in the United States or European Union, e.g., in eCTD-ready format.

# 2.1.5 Rights of Reference; Use of Data.

2.1.5.(a) Subject to <u>Section 2.3.4</u>, when applicable, each Party (the "*Beneficiary*") shall have the right to cross-reference, file or incorporate by reference in its respective Territory any Regulatory Materials (and any Data contained therein) filed by the other Party, its Affiliates or Sublicensees (the "*Filing Party*") for the Lead Product, for use by the Beneficiary (and its Affiliates and Sublicensees) solely to Develop, Manufacture and Commercialize the Lead Product in accordance with this Agreement. The Filing Party shall, on written request by the Beneficiary, provide to the Beneficiary, and to any specified Competent Authority, a letter, in the form reasonably required by the Beneficiary, acknowledging that the Beneficiary (and its Affiliates and Sublicensees) has the above rights with respect to any such Regulatory Materials.

2.1.5.(b) The Filing Party will provide, and cause its Affiliates and Sublicensees to provide, reasonable cooperation to the Beneficiary to effect the foregoing rights (including permitting the Beneficiary (and its Affiliates' and Sublicensees') and/or any relevant Competent Authority to inspect any such Regulatory Materials upon reasonable notice).

2.1.5.(c) In the event that the Regulatory Materials to be cross-referenced, filed or incorporated by reference include any DMF of a Third Party manufacturer, such rights of cross-reference, filing or incorporation by reference shall be subject to such obligations and restrictions as the Filing Party may have to such Third Party manufacturer with respect to the use or disclosure of its DMF.

2.1.5.(d) The Beneficiary shall have the right to request primary source data ("*Raw Data*") for any Data intended for submission by the Beneficiary (or its Affiliates and Sublicensees) to the Competent

31

Authorities or to request that the Filing Party make such Raw Data available for inspection by any applicable Competent Authorities, such right to be exercised in good faith but at the Beneficiary's (or its Affiliates' and Sublicensees') sole discretion. The Filing Party agrees to conduct appropriate quality control and verification procedures and such other processes as may be required to confirm that the Data accurately describes the experimental methods and results of any study. Such quality control and verification procedures shall include verification against Raw Data to ensure that supporting statements and conclusions embodied in any documents submitted by the Beneficiary (and its Affiliates and Sublicensees) to the Competent Authorities are accurately represented. The Filing Party will ensure that quality control and verification procedures are conducted by individuals and entities with the appropriate technical expertise and experience, and that quality control and verification procedures are documented appropriately in compliance with the industry standard SOP's and all applicable laws and regulations.

2.1.5.(e) <u>Disclaimer</u>. Other than as expressly set forth in this Agreement, any Data disclosed or materials (other than pursuant to a Supply Agreement) provided by a Party to the other Party under this Agreement is provided on an "as is" basis, without any warranty (express or implied) of any kind, and the disclosing Party expressly disclaims all such warranties to the maximum extent permitted under applicable Law. The Beneficiary on behalf of itself and its Affiliates and Sublicensees accepts all risk and liability in relation to the use of the Data or materials received from the Filing Party under this Agreement. For avoidance of doubt, this <u>Section 2.1.5.(e)</u> does not limit either Party's rights with respect to the other Party's breach of this Agreement.

#### Section 2.2 Governance; Committees.

2.2.1 <u>Joint Executive Committee</u>. Within thirty (30) days after the Effective Date, the Parties shall establish a joint executive committee (the "*Joint Executive Committee*" or "*JEC*"). The JEC membership and procedures are further described in <u>Section 2.2.5</u>.

2.2.1.(a) The JEC shall in particular, in accordance with the decision-making principles set forth in <u>Section 2.2.5</u>, manage the overall alliance and resolve any disputed matter of the JSC.

2.2.1.(b) Unless otherwise agreed upon between the Parties, the JEC shall be comprised of an equal number of representatives from each of Servier and Pieris, which, unless otherwise agreed upon between the Parties, shall be two (2) members of each Party.

32

2.2.1.(c) The JEC will meet at least once per Calendar Year (or more if agreed upon), with the Co-Chairs (as defined below) attending in person.

2.2.2 <u>Joint Steering Committee</u>. Within thirty (30) days after the Effective Date, the Parties shall establish a joint steering committee (the "*Joint Steering Committee*" or "*JSC*").

2.2.2.(a) The JSC will assume a general role of leadership in the collaboration, to oversee and guide the implementation of the strategic objectives of the project and will be responsible for:

(i) reviewing and approving the Joint Development Plan and Joint Development Budget and any annual or interim updates and proposed amendments thereto;

- (ii) attempting to resolve issues presented to it in accordance with <u>Section 2.2.5</u>;
- (iii) establishing, as appropriate, any additional sub-committees and Working Groups; and
- (iv) making such determinations as are expressly delegated to it under the terms of this Agreement.

2.2.2.(b) Unless otherwise agreed upon between the Parties, the JSC shall be comprised of an equal number of representatives from each of Servier and Pieris, which unless otherwise agreed upon between the Parties, shall be comprised of three (3) members of each Party.

2.2.2.(c) The JSC will meet two (2) to three (3) times each Calendar Year (or more if agreed upon), with the Co-Chairs attending in person at least once per Calendar Year.

2.2.3 <u>Joint Development Committee</u>. Within thirty (30) days after the Effective Date, the Parties shall establish a joint development committee (the "*Joint Development Committee*" or "*JDC*").

2.2.3.(a) The JDC will be responsible for:

(i) Initiating, implementing and overseeing the conduct of the Joint Development Plan;

(ii) preparing updates and proposed amendments Joint Development Plan and Joint Development Budget to be submitted to the JSC;

#### 33

(iii) reviewing any proposed Territory Specific Work, Unsponsored Work, and proposed Additional Studies;

(iv) coordinating the activities of the Parties under this Agreement, including facilitating communications between the Parties with respect to the Development and Manufacture of the Lead Product;

- (v) providing a forum for discussion of the Development and Manufacture of the Lead Product;
- (vi) providing a forum for discussion of the Development and regulatory strategies for the Lead Product;
- (vii) coordinating the sharing of data under Section 3.3.4; and
- (viii) making such determinations as are expressly delegated to it under the terms of this Agreement.

2.2.3.(b) Unless otherwise agreed upon between the Parties, the JDC shall be comprised of an equal number of representatives from each of Servier and Pieris, which unless otherwise agreed upon between the Parties, shall be comprised of between three (3) and five (5) members of each Party. The JDC will put in place a mixed core team in order to work efficiently.

2.2.3.(c) The JDC will meet at least once each Calendar Quarter (or more if agreed upon), with the Co-Chairs attending in person at least twice per Calendar Year.

2.2.4 Joint Intellectual Property Committee. Within thirty (30) days after the Effective Date, the Parties shall establish a joint intellectual property committee (the "*Joint Intellectual Property Committee*" or "*JIPC*").

2.2.4.(a) The JIPC will be responsible for:

(i) overseeing all intellectual property related issues arising under this Agreement, including strategies for prosecution and maintenance of all Pieris IP, Servier IP, and Joint IP with the exception of Pieris Platform IP and Pieris Platform Improvement IP;

- (ii) preparing reports and guidance related to such intellectual property issues to be submitted to the JSC; and
- (iii) making such determinations as are expressly delegated to it under the terms of this Agreement.

#### 34

2.2.4.(b) Unless otherwise agreed upon between the Parties, the JIPC shall be comprised of one (1) or two (2) members of each Party. All JIPC representatives will have appropriate expertise, seniority, decision-making authority and ongoing familiarity with the subject matter of this Agreement and each Party's representatives collectively will have relevant expertise in intellectual property portfolio management and licensing matters.

2.2.4.(c) The JIPC will meet at least twice each Calendar Year (or more if agreed upon), with the Co-Chairs attending in person at least twice per Calendar Year.

#### 2.2.5 General Rules.

2.2.5.(a) <u>Committee Membership</u>. Each of the Joint Executive Committee, Joint Steering Committee, Joint Research Committee, Joint Development Committee and Joint Intellectual Property Committee (each, a "*Committee*") will have solely the roles and responsibilities assigned to it in this <u>Section 2.2</u> and as otherwise expressly set forth in this Agreement. Either Party may replace its respective Committee representatives at any time with prior written notice to the other Party. In the event a Committee member from either Party is unable to attend or participate in a Committee meeting, the Party who designated such representative may designate a substitute representative for the meeting in its sole discretion. The Alliance Managers (as defined below) appointed by Servier and Pieris are ex-officio members of each of the Committees. For avoidance of doubt, the Alliance Manager may also be a member of one or more Committees and either Party may include the same individual on one or more Committees.

2.2.5.(b) <u>Co-Chairs</u>. Each Party shall appoint one of its members in each Committee to co-chair such Committee's meetings (each, a "*Co-Chair*"). The Co-Chairs shall (a) ensure the orderly conduct of the Committee's meetings, (b) attend each Committee meeting (either in-person, by videoconference or telephonically, unless otherwise expressly provided herein), and (c) prepare and issue written minutes of each meeting within thirty (30) days thereafter accurately reflecting the discussions and decisions of such meeting. Unless otherwise agreed, the Committee shall have at least one (1) representative with relevant decision-making authority from each Party such that the Committee is able to effectuate all of its decisions within the scope of its responsibilities. In the event the Co-Chair from either Party is unable to attend or participate in a Committee meeting, the Party who designated such Co-Chair may designate a substitute Co-Chair for the meeting in its sole discretion

35

2.2.5.(c) <u>Committee Meetings.</u> All Committee meetings may be conducted by telephone, video-conference or in person as determined by the Co-Chairs in consultation with the Alliance Managers. Each Party shall bear its own personnel and travel costs and expenses relating to Committee meetings. With the consent of the Parties (not to be withheld unreasonably), other employee representatives of the Parties may attend any Committee meeting as non-voting observers. Either Party may also call a special meeting of a Committee (by videoconference or teleconference) by at least five (5) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and no later than five (5) Business Days prior to the special meeting, such Party shall provide the Committee with materials reasonably adequate to enable an informed decision.

#### 2.2.6 Decision Making.

2.2.6.(a) Other than as set forth herein, in order to make any decision required of it hereunder with respect to any approval, a Committee must have present (in person, by videoconference or telephonically) at least the Co-Chair of each Party (or his/her designee for such meeting). The Parties will endeavor to make decisions where required with respect to any approval of a Committee by consensus of the Co-Chairs. If a dispute or failure to agree arises which cannot be resolved at the JRC, JDC or the JIPC, the Co-Chairs of either Party may cause such dispute or failure to agree to be referred to the Joint Steering Committee for resolution.

2.2.6.(b) If any such dispute or failure to agree arises which cannot be resolved within the Joint Steering Committee, the Co-Chairs of either Party may cause such dispute or failure to agree to be referred to JEC. The JEC shall attempt in good faith to resolve such dispute or failure to agree by unanimous consent (with the Co-Chairs having each one vote). If the JEC cannot resolve such dispute or failure to agree within thirty (30) days of the matter being referred to it, such matter shall be resolved as follows:

(i) each Party shall have final decision-making authority for the Lead Product Development matters related to its respective Territory, provided that such decision is not reasonably expected to have a Material Adverse Effect on the Development, Manufacture or Commercialization of the Lead Product in the other Party's Territory; and

(ii) any revision of the Joint Development Plan and Joint Development Budget shall be a mutual consent decision. For avoidance of doubt, neither Party shall be committed to make any

36

expenditures that are not agreed to by such Party in a Joint Development Budget and neither Party shall be committed to expend funds in excess of that agreed to in a Joint Development Budget without its consent subject to <u>Section</u> <u>4.2.2.(d)</u>.

2.2.6.(c) Each Party shall be responsible and shall have full decision-making authority for the Commercialization of the Lead Product in its respective Territory, provided that such decision is not reasonably expected to have a Material Adverse Effect on the Development, Manufacture or Commercialization of the Lead Product in the other Party's respective Territory.

2.2.6.(d) For the purposes of this Agreement, "*Material Adverse Effect*" shall mean any materially adverse impact on the value of the Lead Product, including but not limited to restriction on the Lead Product's label or adverse impact to the safety or efficacy of the Lead Product.

2.2.6.(e) Disputes that cannot be resolved by the JEC shall be addressed as provided in <u>Section 13.3</u>.

2.2.7 <u>Working Groups</u>. From time to time, a Committee may establish and delegate duties to sub-committees or teams (each, a "*Working Group*") to oversee particular projects or activities within their respective authority. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the Committee that established such Working Group. In no event shall the authority of any Working Group exceed that specified for the Committee under which such Working Group is established, as set forth in this <u>Section 2.2</u>.

2.2.8 <u>Alliance Managers</u>. Within thirty (30) days following the Effective Date, each Party shall appoint an individual to act as alliance manager for such Party (each, an "*Alliance Manager*"). Each Alliance Manager shall be a representative of the applicable Party on the Co-Chair. The Alliance Managers shall coordinate all contacts between the Parties regarding the activities contemplated by this Agreement, facilitate all such activities hereunder, be responsible for progressing the alliance activities, otherwise facilitating communication and be the first line of dispute resolution. The Alliance Managers shall have the right to attend all Committee meetings and shall be responsible for assisting the Co-Chair in performing its oversight responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement(s) chosen by such Party, in its sole discretion, from time to time shall be provided to the other Party. Each Party shall provide its Alliance Manager with sufficient resources for the Alliance Manager to perform his or her role under this Agreement.

2.2.9 <u>Scope of Governance</u>. Notwithstanding the creation of the Committees, each Party shall retain the rights, powers and discretion granted to it hereunder,

#### 37

and no Committee shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. No Committee shall have the power to amend or modify this Agreement, and no decision of any Committee shall be in contravention of any terms and conditions of this Agreement. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder and in no event shall the Alliance Managers have any right or power to modify or amend this Agreement. It is understood and agreed that issues to be formally decided by any of the Committees are only those specific issues that are expressly provided in this Agreement to be decided by such Committee.

#### Section 2.3 Development.

#### 2.3.1 Generally.

2.3.1.(a) <u>Joint Development Plan</u>. Beginning on the Effective Date, the Parties shall jointly Develop the Lead Product in accordance with the pre-clinical and clinical development plan attached to this Agreement as <u>Exhibit 2.3.1.(a)</u>, as may be supplemented and amended from time to time by the Joint Steering Committee, as described in <u>Section 2.2.2.(a)</u> ("*Joint Development Plan*"). The Joint Development Plan shall set forth the research and Development activities to be conducted by the Parties in order to achieve Marketing Approval from [\*\*\*] for the Lead Product and will describe the scope, the budget and the activities to be performed by both Parties, among other items. The Parties acknowledge and agree that the initial Joint Development Plan attached as <u>Exhibit 2.3.1.(a)</u> as of the Effective Date will set forth those Development activities to be conducted by the Parties through first-in-man trial and reasonably in advance of (but at least [\*\*\*] prior to) the expected completion of such Development activities under the initial Joint Development Plan, the Parties (through the JSC as contemplated in this Agreement) shall update and amend such initial Joint Development Plan to comply with the requirements of the immediately preceding sentence.

2.3.1.(b) <u>Responsibility</u>. Subject to the activities allocated to each Party under the Joint Development Plan, Pieris shall be solely responsible for obtaining Regulatory Approvals for the Lead Product in the Pieris Territory and for Development activities to be undertaken in connection therewith, and Servier shall be solely responsible for obtaining Regulatory Approvals for the Lead Product in the Servier Territory and for Development activities to be undertaken in connection therewith. Notwithstanding the foregoing, the Parties agree that to the extent appropriate, Clinical Studies under the Joint Development Plan will be conducted globally with one sponsor per study and unless otherwise mutually agreed by the Parties in writing, on a Clinical Study-by-Clinical

38

Study basis (i) Pieris shall be the sponsor for each Clinical Study conducted in the Pieris Territory under the Joint Development Plan other than as part of a global Clinical Study and (ii) Servier shall be the sponsor for (A) each Clinical Study conducted in the Servier Territory, and (B) each global Clinical Study conducted in both Servier Territory and Pieris Territory under the Joint Development Plan, provided, that notwithstanding the foregoing (i) and (ii), following any Change of Control of Pieris, the JDC shall determine which Party shall be the sponsor for each global Clinical Study conducted in the Territory under the Joint Development Plan depending on each Party's resources and expertise, and with the intent that each Party be the global sponsor of an equal number of global Clinical Studies. Each Party shall be solely responsible for its own Territory Specific Work and any Unsponsored Work.

2.3.1.(c) <u>Database</u>. Before commencement of each Clinical Study pursuant to the Joint Development Plan, the Parties shall use the applicable regulatory database format in order to fulfill both FDA and EMA requirements.

#### 2.3.2 Development Funding.

2.3.2.(a) <u>Joint Development Plan</u>. Starting on the Effective Date, each Party shall be responsible for its Agreed Percentage of the Shared Costs for the Lead Product, as set forth in the budget associated with the then current Joint Development Plan ("*Joint Development Budget*") as included in <u>Exhibit 2.3.1.(a)</u>. Each Party shall be responsible for any other costs such Party incurs in connection with the Development of the Lead Product.

2.3.2.(b) <u>Territory Specific Work and any Unsponsored Work</u> Each Party shall be solely responsible for costs it incurs in the performance of any Territory Specific Work and any Unsponsored Work.

2.3.3 <u>Additional Studies</u>. If a Party (including through its Affiliates or Sublicensees) wishes to conduct one or more additional Clinical Studies, Non-Clinical Development or Translational Research activities for the Lead Product in the Field which Data could be used in the other Party's respective Territory (beyond what is then included in the Joint Development Plan or any Territory Specific Work) in the Field for Development of the Lead Product, such Party (the "*Proposing Party*") shall notify the other Party (the "*Non-Proposing Party*") of such proposed studies (the "*Proposed Study(ies)*") and provide the Non-Proposing Party with any supporting Data or publications supporting any such proposal. In such event, the JDC shall consider such proposal and evaluate the supporting Data and information in good faith.

39

2.3.3.(a) If the Parties both wish to collaborate in the conduct of such Proposed Study(ies), the Proposing Party shall prepare an amendment to the Joint Development Plan and Development Budget to include the Proposed Study(ies) for review and approval by the JSC.

2.3.3.(b) If, after consideration in good faith by the JDC and the JSC, as applicable, the Parties do not, within [\*\*\*], mutually agree to include the Proposed Study(ies) in the Joint Development Plan, the Proposing Party may elect to conduct such rejected Proposed Study(ies) (such study(ies), in such event, "*Unsponsored Work*"). The Non-Proposing Party may, within [\*\*\*] following the failure of the JDC to mutually agreed to include the Proposed Study(ies) in the Joint Development Plan (the "*Objection Period*"), provide reasonable written objection to such Unsponsored Work on the basis of likely potential Material Adverse Effect upon the procurement or maintenance of Regulatory Approval or Commercialization of the Lead Product in the Non-Proposing Party's respective Territory. If the Non-Proposing Party makes such an objection, the Proposing Party shall not be permitted to proceed with such Unsponsored Work unless the Proposing Party can establish that such Unsponsored Work is Territory Specific Work, required to achieve Regulatory Approval in [\*\*\*] or in [\*\*\*]. If the Proposing Party is able to establish that such Unsponsored Work at its sole expense. The Proposing Party shall deliver to the JSC regular updates on such Unsponsored Work, and promptly following completion of the Unsponsored Work, a top-line summary of all Data resulting from such Unsponsored Work.

2.3.3.(c) <u>Clinical Studies in the Other Party's Territory</u>. In the event that, in furtherance of its Development activities for the Lead Product in its respective Territory and in accordance with its rights under this Agreement, a Party believes it needs to conduct Clinical Studies which include one or more sites in the other Party's Territory, then the requesting Party shall provide written notice to the JDC of the proposed trial design (including the most current protocol draft), study size (estimated number of patients), the list of proposed countries involved in the study and the purpose of and need for such study. The proposing Party shall not proceed with such Clinical Study without the other Party's consent through the JSC, which shall not be unreasonably withheld or delayed.

# 2.3.4 Ownership and Use Rights of Development Data; Additional Study Data.

2.3.4.(a) <u>Development Data</u>. The Parties shall jointly own any Data arising out of each Party's performance of its activities under the Joint Development Plan ("*Development Data*") and, subject to <u>ARTICLE 8</u> and

40

<u>ARTICLE 9</u>, each Party shall be free to use and exploit such Development Data for the purposes of exercising its rights and fulfilling its obligations under this Agreement. For the avoidance of doubt, Development Data shall not include any Data resulting from any Territory Specific Work or Unsponsored Work (collectively, "*Additional Study Data*").

2.3.4.(b) Additional Study Data. All Additional Study Data shall be solely owned by the Party that performed the Territory Specific Work or Unsponsored Work that produced such Data, subject to the rights and licenses, if any, granted to the other Party herein. Each Party shall have access to and the right to use at no cost to such Party all Data resulting from Unsponsored Work and Territory Specific Work conducted by or on behalf of the other Party, its Affiliates and its Sublicensees, solely as necessary to comply with safety reporting or other similar regulatory requirements in its respective Territory, but not, for example, for Marketing Approval or pricing approval. If the Non-Proposing Party wishes to obtain access to and have the right to use the other Party's Additional Study Data for any other reason (including obtaining Marketing Approval or pricing approval), it may do so by notice in writing to the Proposing Party at any time, provided that upon the exercise of such right, the Non-Proposing Party shall reimburse the Proposing Party for the cost it would have otherwise paid if it had agreed to co-fund such Unsponsored Work plus a premium of [\*\*\*]. For clarification purposes only, if Servier were the Non-Proposing Party in the scenario described in the directly preceding sentence, Servier will reimburse Pieris for [\*\*\*] of Pieris' costs that would have been Shared Costs if it had been conducted under a Joint Development Plan) incurred in obtaining such Additional Study Data, and if Pieris were the Non-Proposing Party in the scenario described in the directly preceding sentence, Pieris will reimburse Servier for [\*\*\*] of Servier's costs that would have been Shared Costs if it had been conducted under a Joint Development Plan and are incurred in obtaining such Additional Study Data.

2.3.5 <u>Reporting: Development Records</u>. Each Party shall provide to the other written reports regarding the progress and results of their activities under the Joint Development Plan through the JDC. Each Party shall (and shall cause its Affiliates, Sublicensees, subcontractors and consultants to) maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf (including by its Affiliates, Sublicensees, subcontractors and consultants) under the Joint Development Plan. Such records, including any electronic files where such Data may also be contained, shall fully and properly reflect all work done and results achieved in sufficient detail and in a good scientific manner appropriate for patent and regulatory purposes. Each Party shall have the right to review and receive a copy of such records (including a copy of the databases) maintained by the other Party (including its Affiliates, Sublicensees, subcontractors and consultants) at

41

reasonable times, but no more than twice in any one Calendar Year, and to obtain access to source documents to the extent needed for patent or regulatory purposes or for other legal proceedings. The Parties may agree to set up an electronic data room, SharePoint or a relevant database in order to manage the exchange of information of all on-going activities in a secure manner.

2.3.6 <u>Subcontractors</u>. Each Party will have the right to use its Affiliates or Third Parties to perform the Development, Manufacturing and Commercialization activities for the benefit of such Party under this Agreement; provided that: (a) such Party remains responsible for the work allocated to such Party hereunder (including under the Joint Development Plan), and payment to, such subcontractors as it selects to the same extent it would if it had done such work itself; and (b) such Party will enter into a binding written agreement with such Affiliate and each such Third Party, prior to commencing such activities, which agreement includes the following terms (i) the subcontractors undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to <u>ARTICLE 8</u>, and (ii) such Party Controls all intellectual property developed by the subcontractors in the course of performing any such work and owns all such intellectual property that is specifically related to, or otherwise necessary for Development, Manufacture or Commercialization of, the Product, which includes, prior to commencing any such activities, having such subcontractor execute an agreement licensing or assigning, as applicable, any inventions and related Intellectual Property Rights to the Party by whom they are employed or for whom they are providing services (or its designated Affiliate). Notwithstanding the foregoing in this <u>Section 2.3.6</u>, where the Third Party is an academic or academic institution, the Parties shall consider in good faith to agree to waive clause (ii); for all other Third Parties, the Parties must mutually consent to waive or limit clause (ii), such consent not to be unreasonably withheld.

#### 2.3.7 <u>Regulatory Matters</u>.

2.3.7.(a) <u>Ownership</u>. Pieris will own all INDs, BLAs and related regulatory documentation submitted to any Competent Authority in the Pieris Territory with respect to the Lead Product. Servier will own all IND/IMPDs, MAA and related regulatory documentation submitted to any Competent Authority in the Servier Territory with respect to the Lead Product as well as any drug master files maintained by or on behalf of Servier anywhere in the world with respect to the Lead Product.

2.3.7.(b) <u>Responsibility</u>. Each will be solely responsible for all regulatory matters relating to Products in its Territory, including (i) overseeing, monitoring and coordinating all regulatory actions, communications and filings with, and submissions to, each Competent Authority; (ii) interfacing, corresponding and meeting with each Competent Authority; (iii) seeking and maintaining all regulatory filings; and (iv) maintaining and submitting all records required to be maintained or required to be submitted to any Competent Authority.

42

## 2.3.7.(c) <u>Communications</u>.

(i) Within [\*\*\*] after receipt of any Health Authority Communication from a Competent Authority in its Territory with respect to the Lead Product, the recipient Party will provide the other Party, through its Alliance Manager, with a brief written description of the principal issues raised in such Health Authority Communication and, upon such other Party's request, the recipient Party will also provide complete copies of such correspondence within a reasonable period of time following such request. The recipient Party will allow such other Party a reasonable opportunity to review and comment on any proposed response to such Health Authority Communications in advance of the transmission of such response, and will reasonably consider all comments timely provided in connection therewith.

(ii) Within [\*\*\*] after receipt of any Health Authority Communications from a Competent Authority in its Territory related to a Clinical Study hold or potential Clinical Study hold for safety reasons or for a potential withdrawal from the market for a safety issue or a report of a serious safety finding by a Competent Authority, the recipient Party will provide the other Party, through its Alliance Manager, with a brief written description of the principal issues raised in such Health Authority Communication.

2.3.7.(d) <u>Meetings</u>. Each Party shall provide the other Party with reasonable advance notice of all formal meetings and teleconferences with the FDA with respect to Pieris and the EMA with respect to Servier pertaining to the Lead Product, or with as much advance notice as practicable under the circumstances. The notifying Party shall use reasonable efforts, to the extent reasonably practicable, to permit the other Party to have, at such other Party's expense, mutually acceptable representatives attend as observers, such formal meetings and teleconferences with FDA or EMA pertaining to such Product provided, however, that such notifying Party shall not be obligated to change or re-schedule any such meeting in order to accommodate the schedule of the other Party's representatives.

2.3.7.(e) <u>Submissions</u>. With respect to the Lead Product, each Party will allow the other Party a reasonable opportunity to review and comment on all filings and other submissions to the FDA and the EMA, as applicable, related to such Product in advance of submission of any such filings, and such first Party will reasonably consider all comments timely provided by such other Party in connection therewith.

43

2.3.7.(f) <u>Pharmacovigilance Agreement/Safety Data Exchange Agreement</u>. After the Effective Date, the Parties shall mutually agree on a reasonably practicable date to enter into an agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to the Lead Product (the "*Pharmacovigilance Agreement*"). The Pharmacovigilance Agreement shall be executed before the initiation of the first Clinical Study conducted by either of the Parties for a Product that requires the other Party to report pharmacovigilance data generated by such Clinical Study to the Competent Authorities. When executed, the Pharmacovigilance Agreement shall remain a stand-alone document, independent from this Agreement to enable amendment thereto as required independently of this Agreement.

2.3.7.(g) <u>Specifications</u>. The Pharmacovigilance Agreement shall be in accordance with, and enable both Parties to fulfill, all local, national and regional regulatory reporting obligations under applicable Laws.

### Section 2.4 Manufacturing.

2.4.1 <u>Generally</u>. The Joint Development Plan shall include details regarding Manufacture of the supply of Lead Product until Marketing Approval of the Lead Product.

#### 2.4.2 Responsibility; Technology Transfer.

2.4.2.(a) Immediate Needs for Development Purposes. Pieris shall use Commercially Reasonable Efforts to cause its Third Party contract manufacturers (the "*CMOs*"), subject to a satisfactory audit by Servier, to Manufacture and supply to Servier all of its clinical supply requirements for the Lead Product for clinical use and Development activities (including CMC activities) until the Parties agree on a manufacturing plan in accordance with Section 2.4.2.(b). Until such time, the CMC Costs shall be included as part of Shared Costs and shall be split among the Parties in accordance with its Agreed Percentage. Pieris shall use Commercially Reasonable Efforts to cause its CMOs to enter into three-way quality agreements for Manufacturing and supply of the Lead Product with Servier.

2.4.2.(b) Manufacture for Later Clinical Development and Commercialization.

(i) On a Product-by-Product basis, the Parties shall discuss in good faith and mutually agree (taking into account the guiding

44

principles of cost, quality and speed of manufacture) on which Party will be responsible for the supply of such Product for the conduct of any Clinical Study prior to commercial scale manufacturing, and such Party's manufacturing and supply activities shall be set forth in the applicable Joint Development Plan; provided that Pieris is hereby designated as the Party responsible for the supply of Lead Product for the conduct of the Phase 1 Clinical Study. In addition, the Development Plan shall include the Parties' strategy for commercial scale manufacturing.

1. If the applicable Development Plan allocates responsibility to a Party to itself Manufacture a Product, then within [\*\*\*] of a written request of the other Party, the Parties will negotiate in good faith and enter into a supply agreement (and any other necessary ancillary agreements including a quality technical agreement) for clinical or commercial supply of such Product (each, a "*Party Supply Agreement*") which will be on commercially reasonable terms customary to Third Party contract manufacturing organization supply agreements and shall include key performance indicators (including criteria regarding manufacturing capacity, quantity, timeliness of delivery, quality and cost that are consistent with prevailing industry standards for Third Party contract manufacturing under a Party Supply Agreement will be supplied or clinical purposes prior to commercial scale manufacturing under a Party Supply Agreement will be supplied at a price no greater than the Product's fully burdened cost of goods, and any Product supplied on a commercial scale under a Party Supply Agreement will be supplied at a commercially reasonable price mutually agreed by the Parties in good faith (not to exceed [\*\*\*]).

2. If the applicable Development Plan provides for the Parties to obtain Manufacturing services from a Third Party CMO, then the Parties shall use good faith efforts to enter into supply agreements with the same Third Party CMOs as primary and secondary suppliers of the relevant Product (each such agreement, a ("*CMO Supply Agreement*"). Such agreements may be separately established by each Party but the Parties will use good faith efforts to coordinate the activities under this <u>Section 2.4.2.(b)</u> and to take advantage of any volume discounts or economies of scale. If the Parties do not so elect, then each Party agrees that, in its CMO Supply Agreement, such Party shall not include any limitations on such Third Party's ability to

45

supply the other Party with such Product, and upon the request of the other Party, such Party shall facilitate initial business discussions between the other Party and such Third Party CMO. Any CMO Supply Agreement shall (a) be consistent with the terms included in this Agreement, including with regard to confidentiality, (b) shall assign to the contracting Party such Third Party's entire right, title and interest in, or provide a perpetual, fully-paid, worldwide, fully sublicensable (through multiple tiers) exclusive (other than with respect to such Third Party's background technology and improvements thereof) license under and to, any Know-How or Patent Rights made, developed or invented by such Third Party related to the Manufacture of such Products, and (c) shall be subject to review by the other Party prior to execution.

3. At Servier's request, the applicable Development Plan shall include a technology transfer of manufacturing process(es) owned or Controlled by Pieris, and in Pieris' or its CMOs' possession for the Lead Product to Servier or its Third Party subcontractor. At Servier's request, Pieris shall include in any contract with a CMO for Manufacture of the Lead Product provisions requiring the CMO to conduct such technology transfer as set forth in the Development Plan, including by providing copies or samples of relevant documentation, materials and other embodiments of the relevant Know-How, and by making available its qualified technical personnel on a reasonable basis to consult with Servier with respect to such Know-How. Servier shall reimburse Pieris' reasonable costs in connection with any technology transfer under this <u>Section 2.4.2.(b)</u>. Upon the conclusion of such technology transfer (with no further shared coordination of supply of the Lead Product), each Party shall be solely responsible for and have sole control of, in each case by itself or through one or more CMOs, the Manufacture and supply of the Lead Product for further Development (other than under the Joint Development Plan) or Commercialization in the Party's respective Territory, at such Party's sole cost and expense.

#### Section 2.5 Commercialization.

2.5.1 <u>Generally</u>. The key Commercialization principles for the Lead Product will be set forth in a written summary of the global Commercialization strategy for such Product (each, a "*Global Commercialization Strategy*"). The JSC shall prepare the initial draft of such Global Commercialization Strategy for the Lead

46

Product within [\*\*\*] after initiation of the first Pivotal Clinical Study for such Product, and then annually thereafter. Amendments to any Global Commercialization Strategy will become effective following review and approval by the JSC.

2.5.1.(a) Servier Territory Commercialization Plan. No less than [\*\*\*] in advance of the reasonably expected First Commercial Sale in the Servier Territory with respect to the Lead Product, and on an annual basis thereafter, Servier shall prepare and deliver to the JSC for review a written plan that summarizes the Commercialization activities to be undertaken with respect to such Product in the Servier Territory in the next Calendar Year and, to the extent commercially reasonable and Servier has reasonable visibility at the time, Servier's intended plans and high-level anticipated timelines to obtain further Regulatory Approvals and Commercialize such Product in countries in the Servier Territory in which Servier is not then Commercializing such Product (the "Servier Territory Commercialization Plan"). Each Servier Territory Commercialization Plan shall be consistent with the most recent Global Commercialization Strategy approved by the JSC. The Servier Territory Commercialization Plan for the Lead Product shall subsequently be updated and modified by Servier, from time to time at its discretion and no less frequently than once per Calendar Year, based upon, among other things, Servier's Commercialization activities with respect to such Product in the Servier Territory, a copy of which updated plan will be provided to the JSC for such Product. Notwithstanding the foregoing, in the event of any disagreement between the Parties regarding the Servier Territory Commercialization Plan for a Product, the Servier representatives on the JSC for such Product shall have final decision-making authority over the preparation and updating of such Servier Territory Commercialization Plan, provided that such decisions do not materially adversely affect the Commercialization of such Product in the Pieris Territory.

2.5.1.(b) <u>Pieris Territory Commercialization Plan</u>. No less than [\*\*\*] in advance of the reasonably expected First Commercial Sale in the Pieris Territory with respect to the Lead Product, and on an annual basis thereafter, Pieris shall prepare and deliver to the JSC for such Product for review a written plan that summarizes the Commercialization activities to be undertaken with respect to such Product in the Pieris Territory in the next Calendar Year and, to the extent commercially reasonable and Pieris has reasonable visibility at the time, Pieris' intended plans and high-level anticipated timelines to obtain further Regulatory Approvals and Commercialize such Product in the Pieris Territory (the "*Pieris Territory Commercialization Plan*"). The Pieris Territory Commercialization Plan shall be consistent with the most recent Global Commercialization Strategy approved by the JSC. The Pieris Territory Commercialization Plan for the Lead Product shall subsequently be updated and modified by

47

Pieris, from time to time at its discretion and no less frequently than once per Calendar Year, based upon, among other things, Pieris' Commercialization activities with respect to such Product in the Pieris Territory, a copy of which updated plan will be provided to the JSC for such Product. Notwithstanding the foregoing, in the event of any disagreement between the Parties regarding the Pieris Territory Commercialization Plan for a Product, the Pieris representatives on the JSC for such Product shall have final decision-making authority over the preparation and updating of such Pieris Territory Commercialization Plan, provided that such decisions do not materially adversely affect the Commercialization of such Product in the Servier Territory.

2.5.2 <u>Global Branding</u>. The JSC shall, from time to time during the Term, develop (and thereafter modify and update) a highlevel global branding strategy (including global positioning and promotional messages) for each Product for use throughout the world (the "*Global Branding Strategy*"), which shall be consistent with the applicable Global Commercialization Strategy. Each Party shall be responsible for the creation, production and regulatory filings of written sales, promotion and advertising materials for the Products for use in such Party's respective Territory, which such materials shall be compliant with applicable Law and the Global Branding Strategy ("*Promotional Materials*"). Upon one Party's request, the other Party shall provide copies of representatives samples of its final, approved Promotional Materials with respect to [\*\*\*].

2.5.3 <u>Reporting Obligations</u>. Each Party shall report to the JSC in writing, by no later than each March 31 following the first Regulatory Approval of such Product in the Field in such Party's Territory (for the period ending December 31 of the prior Calendar Year), summarizing in reasonable detail such Party's Commercialization activities for such Product in such Party's Territory performed to date (or updating such report for activities performed since the last such report was given hereunder, as applicable).

2.5.4 <u>Warehousing and Distribution</u>. Each Party (or its Sublicensees) shall be responsible for booking sales in its Territory. Each Party may warehouse Products both inside and outside of such Party's Territory, provided that any sales with respect to such Products are booked in such Party's Territory. If a Party receives any orders for any Product in the other Party's Territory, it shall refer such orders to the other Party, to the extent it is not prohibited from doing so under applicable Law. Moreover, each Party and its Affiliates shall be solely responsible for handling all returns of any Product sold in its Territory, as well as all aspects of Product order processing, invoicing and collection, distribution, inventory and receivables of Products sold in its Territory.

2.5.5 <u>Recalls, Market Withdrawals or Corrective Actions</u>. In the event that any Competent Authority issues or requests a recall or takes a similar action in connection with a Product in a Territory, or in the event either Party determines

48

that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of a Product in its Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall, within twenty-four (24) hours of such request, order or determination, notify the other Party's Alliance Manager and JSC members by telephone or e-mail. Each Party, in consultation with the other Party, shall decide whether to conduct a recall of a Product in its own Territory and the manner in which any such recall shall be conducted (except in the case of a government mandated recall, when such Party may act without such advance notice but shall notify the other Party as soon as possible). Except as may otherwise be agreed to by the Parties, each Party shall bear the expense of any such recall in its own Territory. Each Party will make available all of its pertinent records that may be reasonably requested by the other Party in order to effect a recall of a Product in the other Party's Territory. The Parties' rights and obligations under this <u>Section 2.5.5</u> shall be subject to the terms of any Party Supply Agreement(s). In the event of a conflict between the provisions of any such Party Supply Agreement and this <u>Section 2.5.5</u>, the provisions of such Party Supply Agreement shall govern.

#### 2.5.6 Ex-Territory Sales; Export Monitoring.

2.5.6.(a) <u>Ex-Territory Sales</u>. Subject to applicable Law, neither Party (nor any of its Affiliates or Sublicensees) shall engage in any advertising or promotional activities relating to any Product directed primarily to customers or other buyers or users of such Product located outside its Territory or accept orders for Products from or sell Products into such other Party's Territory for its own account, and if a Party receives any order for any Product in the other Party's Territory, it shall refer such orders to the other Party.

2.5.6.(b) <u>Export Monitoring</u>. Each Party and its Affiliates will use Commercially Reasonable Efforts to monitor and prevent exports of Products from its own Territory for Commercialization in the other Party's Territory using methods permitted under applicable Law that are commonly used in the industry for such purpose (if any), and shall promptly inform the other Party of any such exports of Products from its Territory, and any actions taken to prevent such exports. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with Law to prevent exports of Products from its Territory for Commercialization in the other Party's Territory.

#### Section 2.6 Payments and Milestones.

2.6.1 <u>Upfront Fee</u>. In partial consideration for the rights granted under this Agreement regarding the Lead Product, Servier shall pay Pieris a one-time, non-refundable and non-creditable lump sum payment of [\*\*\*] (the "*Lead Product Upfront Fee*") [\*\*\*] following receipt of the corresponding invoice from Pieris after the Effective Date.

49

2.6.2 <u>Achievement Adjustment</u>. In the event that the Lead Product achieves Lead Product DCN by the dates specified in the table below, the corresponding adjustment to the Lead Product Upfront Fee specified in the table below shall be made by Servier within [\*\*\*] following receipt of the corresponding invoice from Pieris after such date of achievement of Lead Product DCN.

Date of Achievement of Lead	
Product DCN	Payment Amount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Pieris shall generate all data required for the Lead Product DCN (the "*Required Data*") as set forth in <u>Exhibit 1.141</u>. Pieris shall notify Servier when all Required Data are accessible to Servier through an electronic data room and whether the Lead Product DCN criteria as set forth in <u>Exhibit 1.141</u> are met (the "*Access Notice*"). Servier has [\*\*\*] to confirm in writing the completeness of the Required Data or request the missing information, in which case, the Access Notice shall not be deemed valid, Pieris shall provide the missing information and the procedure of the foregoing sentence will apply again.

Upon Servier's confirmation that the Required Data is complete, (a) if the success criteria are met, the date of the Lead Product DCN shall be the date of receipt by Servier of the Access Notice and (b) if the success criteria are not met, the Parties will have [\*\*\*] to decide whether or not they wish to continue the Development of the Lead Product, in which case, upon Servier's decision to continue the Development of the Lead Product DCN shall be the date of receipt by Servier of the Access Notice.

2.6.3 <u>Development and Regulatory Milestones</u>. In partial consideration for the rights granted under this Agreement regarding the Lead Product, in each case upon initial achievement of the applicable milestone by or on behalf of Servier or Servier's Affiliates or Sublicensees for the Lead Product, Servier will pay Pieris the one-time, non-refundable and non-creditable lump sum payments set forth below.

	Payment Amount				
Development Event	1st Indication	2nd Indication	3rd Indication	4th Indication	5th Indication and beyond
Start of GLP Tox Studies	[***]	[***]	[***]	[***]	[***]
Start of Phase 1 Clinical Study	[***]	[***]	[***]	[***]	[***]
Start of Phase 2a Clinical Study or Phase 1					
Clinical Study Expansion Cohorts	[***]	[***]	[***]	[***]	[***]
Start of Pivotal Clinical Study	[***]	[***]	[***]	[***]	[***]
[***] filing [***]	[***]	[***]	[***]	[***]	[***]
[***] filing [***]	[***]	[***]	[***]	[***]	[***]
Marketing Approval [***]	[***]	[***]	[***]	[***]	[***]
Marketing Approval [***]	[***]	[***]	[***]	[***]	[***]
[***] Marketing Approval [***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

Notwithstanding the above, with respect to each Marketing Approval (centralized procedure) in Europe milestone, if the approval is granted but conditional upon the completion of an additional Clinical Study, in lieu of paying the amount corresponding to such approval, Servier will pay [\*\*\*] of such amount upon issuance of the conditional approval and [\*\*\*] of such amount upon issuance of the conditional approval.

2.6.4 <u>Skipped Development and Regulatory Milestones</u>. If any of the above development and regulatory milestones are skipped (i.e. a later milestone payment is payable before an earlier milestone payment within the same jurisdiction if

51

applicable), or if Regulatory Approval is achieved in any jurisdiction with respect to the Lead Product without all of the preceding milestone payments applicable to such Product having been achieved in such jurisdiction if applicable, then the skipped milestone(s) will be deemed to have been achieved upon the achievement of the subsequent milestone or upon Regulatory Approval, as applicable. If the MAA in Europe is filed through another procedure than the centralized procedure, the Parties will discuss in good faith the opportunity to adjust the milestones.

2.6.5 <u>Sales Milestones</u>. As partial consideration for the rights granted hereunder regarding the Lead Product, Servier shall make the non-refundable, non-creditable, one-time sales milestone payments to Pieris based upon the first achievement of the following Calendar Year cumulative Royalty Bearing Net Sales of the Lead Product in the Servier Territory as set forth below.

Annual Calendar Year - Royalty Bearing Net	
Sales Threshold	Payment
[***]	[***]
[***]	[***]
[***]	[***]
Maximum Total	[***]

2.6.6 <u>Royalties</u>. As partial consideration for the rights granted hereunder regarding the Lead Product, during the Royalty Term Servier shall pay Pieris royalties equal to the following percentages of Royalty Bearing Net Sales of the Lead Product over a Calendar Year in the Servier Territory, subject to adjustment as set forth in <u>Section 4.1</u> ("*Lead Product Royalties*"):

Annual Calendar Year Royalty Bearing Net Sales	<b>Royalty Rates owed by Servier</b>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

## **ARTICLE 3 RESEARCH COLLABORATION**

### Section 3.1 Scope.

3.1.1 Generally.

3.1.1.(a) During the Initial Research Collaboration Term, the Parties shall jointly collaborate to generate, evaluate and Develop the Initial Collaboration Products (the "*Initial Research Collaboration*"). The Parties may mutually agree to extend the Initial Research Collaboration Term for up to two (2) one-year terms consecutively applied (each, an "*Initial Research Collaboration Renewal Term*").

#### 52

3.1.1.(b) The Initial Research Collaboration shall encompass four (4) Bispecific Products (the "*Initial Collaboration Products*"). A list of the initial Collaboration Products is included in <u>Schedule 3.1.1.(b)</u>; this list may be modified and will be completed by the Parties during the course of the Research Collaboration, in each case by mutual written agreement of the Parties.

3.1.1.(c) Additional Research Collaboration. Servier shall have an option (exercisable in Servier's sole discretion) to jointly collaborate with Pieris to generate, evaluate and Develop the Additional Collaboration Products under this Agreement (the "Additional Research Collaboration" and such option, the "Servier Collaboration Option"). In order to exercise the Servier Collaboration Option under this Section 3.1.1.(c), Servier shall provide Pieris written notice stating its desire to opt-in with respect to the Additional Research Collaboration (such notice, the "Servier Opt-In Notice") no later than the end of the Initial Research Collaboration Term (the "Servier Collaboration Option Period"). In the event that Servier delivers such Servier Opt-In Notice to Pieris prior to the end of the Servier Collaboration Option Period, then the Parties shall, within [\*\*\*] thereof, negotiate in good faith to mutually agree upon the applicable Additional Collaboration of such Additional Research Collaboration Additional Research Collaboration along with the duration (start and completion) of such Additional Research Collaboration Option Fee in accordance with Section 3.6.1.(b). The Parties may mutually agree to extend the Additional Research Collaboration Term for up to two (2) one-year terms consecutively applied (each, an "Additional Research Collaboration Renewal Term").

3.1.1.(d) The Additional Research Collaboration shall encompass up to three (3) Bispecific Products or [\*\*\*], such Bispecific Products [\*\*\*] to be mutually agreed by the Parties in accordance with <u>Section 3.1.1.(c)</u>, one (1) of which shall be designated by both Parties as a Pieris Designated CoDev Collaboration Product (the "*Additional Collaboration Products*").

### 3.1.2 Collaboration Plan.

3.1.2.(a) The Parties shall establish a research pre-clinical and clinical development plan for each Collaboration Product, as may be supplemented and amended from time to time by the Joint Steering Committee, as described in <u>Section 2.2.2.(a)</u> (each, a "*Collaboration Plan*"). The initial Collaboration Plan for the Initial Collaboration Products shall be attached hereto as <u>Exhibit 3.1.2.(a).1</u>, <u>Exhibit 3.1.2.(a).2</u>, <u>Exhibit 3.1.2.(a).3</u> and <u>Exhibit 3.1.2.(a).4</u>. Subject to Servier's exercise of the Servier Collaboration Option in accordance with <u>Section 3.1.1.(c)</u>, the

53

Parties shall within ninety (90) days of the exercise of the Servier Collaboration Option, prepare an initial Collaboration Plan for the three (3) Additional Collaboration Products, each of which shall be attached hereto as <u>Exhibit 3.1.2.(a).5</u>, <u>Exhibit 3.1.2.(a).6</u> and <u>Exhibit 3.1.2.(a).7</u>. Each Collaboration Plan shall set forth the research and Development activities to be conducted regarding the Collaboration Products by the Parties up to [\*\*\*] and the terms of, and activities therein, shall at all times be designed to be in compliance with all applicable Laws and in accordance with professional and ethical standards customary in the biopharmaceutical industry. In the event that, during the Collaboration Term, the Parties mutually agree to drop a Collaboration Product (in accordance with <u>Section 5.2.1</u>) and replace such product with a new Bispecific Product, the Collaboration Plan shall be updated to reflect the new Bispecific Product and research and Development activities related thereto.

3.1.2.(b) With respect to a Collaboration Product that constitutes a Pieris Designated CoDev Collaboration Product, (i) [\*\*\*] prior to the anticipated [\*\*\*] date, the Parties shall in good faith prepare an update to the Collaboration Plan which sets forth the proposed Development activities to be conducted by the Parties (along with a corresponding updated Collaboration Budget) up to a Phase 2a Clinical Study, for such Pieris Designated CoDev Collaboration Product, and (ii) upon such Pieris Designated CoDev Collaboration Product actor accordance with Section 3.1.4.(a), the Collaboration Plan for such Product will be replaced by an updated Collaboration Plan that shall set forth the research and Development activities to be conducted by the Parties in order to achieve Marketing Approval from [\*\*\*] for such CoDev Collaboration Product, and the provisions of Section 2.3, Section 2.4 and Section 2.5 shall apply to such Product *mutatis mutandis* except that the Parties shall agree upon responsibility for Manufacturing such Product for the Phase 1 Study and it shall not automatically be the responsibility of Pieris.

54

### 3.1.3 Collaboration Obligations.

3.1.3.(a) Each Party shall conduct the activities assigned to such Party under each Collaboration Plan in accordance with the timelines set forth therein.

3.1.3.(b) The provisions of <u>Section 2.3.4.(a)</u> (Ownership and Use Rights of Collaboration Data), <u>Section 2.3.5</u> (Reporting; Development Records) and <u>Section 2.3.6</u> (Subcontractors) shall apply *mutatis mutandis* to the activities of the Parties pursuant to a Collaboration Plan.

3.1.4 <u>Co-Development Option</u>. On a Pieris Designated CoDev Collaboration Product-by-Pieris Designated CoDev Collaboration Product basis, within [\*\*\*] after the written acknowledgement by the Parties that [\*\*\*] has been achieved (the "*Consideration Period*"), Pieris shall have (and Servier hereby grants to Pieris as of the Effective Date) the exclusive option (exercisable in Pieris' sole discretion) to opt into global co-Development and Commercialization of each such Pieris Designated CoDev Collaboration Product(s) (each a "*Pieris Co-Development Option*"). The Parties shall use Commercially Reasonable Efforts to agree as to the updated Collaboration Product [\*\*\*] prior to the anticipated achievement of [\*\*\*]. In order to exercise its option under this <u>Section 3.1.4</u>, Pieris shall provide Servier written notice stating its desire to opt-in with respect to the applicable Pieris Designated CoDev Collaboration Product (such notice, the "*Opt-In Notice*") within the Consideration Period.

3.1.4.(a) <u>CoDev Collaboration Products</u>. Upon receipt of the Opt-In Notice by Servier, the Pieris Designated CoDev Collaboration Product(s) identified in such Opt-In Notice shall automatically be deemed to be a co-development product (each, a "*CoDev Collaboration Product*" and collectively, the "*CoDev Collaboration Products*").

### 3.1.4.(b) Servier WW Collaboration Products.

(i) Pieris Designated CoDev Collaboration Products shall automatically be deemed Servier WW Collaboration Products after expiration of the Consideration Period unless Pieris exercises its Pieris Co-Development Option for such Pieris Designated CoDev Collaboration Product within the Consideration Period (each such Pieris Designated CoDev Collaboration Product s for which such option was not exercised, and any other Collaboration Product that does not constitute a CoDev Collaboration Product, each, a "*Servier WW Collaboration Product*" and collectively, the "*Servier WW Collaboration Products*").

(ii) In the event that Pieris fails to exercise the Pieris Co-Development Option for one or more Pieris Designated CoDev

55

Collaboration Products within the Consideration Period (each a "*Declined Option Collaboration Product*") and Servier wishes to continue the Development and Commercialization of such Declined Option Collaboration Product as a Servier WW Collaboration Product, Servier will reimburse Pieris for [\*\*\*] of Pieris' Agreed Percentage of the costs incurred in the Development of such Declined Option Collaboration Product under the applicable Collaboration Plan. Servier shall notify Pieris of its election to continue Development and Commercialization of such Declined Option Collaboration Product (a "*DOCP Election Notice*") within [\*\*\*] of the end of the respective Consideration Period. In the event that Servier does not provide Pieris the DOCP Election Notice within [\*\*\*] of the end of the respective Consideration Period or affirmative elects not to continue Development and Commercialization of such Declined Option Collaboration Product, such Declined Option Collaboration Product shall constitute a Dropped Product by Servier for purposes of <u>Section 5.2.1</u> effective as of the end of [\*\*\*] period or as of the date that notice is given to Pieris.

(iii) If [\*\*\*], any Collaboration Product becomes a Servier WW Collaboration Product, Servier will be solely responsible for all pre-clinical and clinical Development, Manufacture and worldwide Commercialization of such Servier WW Collaboration Product.

3.1.5 <u>Reallocation of CoDev Collaboration Products and Servier WW Collaboration Products</u>. Notwithstanding <u>Section 3.1.4</u>, if all of the CoDev Collaboration Products or all of the Servier WW Collaboration Products fail to reach [\*\*\*], then one Collaboration Product shall be reallocated as follows:

3.1.5.(a) In the event that no Servier WW Collaboration Products have reached [\*\*\*] by the time the second CoDev Collaboration Product has reached [\*\*\*] in the Pieris Territory, at Servier's written election, unless otherwise agreed by the Parties, such second CoDev Collaboration Product to reach [\*\*\*] shall automatically be converted to a Servier WW Collaboration Product. Servier shall reimburse Pieris for its share of the Shared Costs paid during the time that such Collaboration Product was a CoDev Collaboration Product.

3.1.5.(b) In the event that no CoDev Collaboration Products have reached [\*\*\*] by the time the second Servier WW Collaboration Product has reached [\*\*\*] in the Servier Territory, at Pieris' written election, unless otherwise agreed by the Parties, such second Servier WW Collaboration Product to reach [\*\*\*] shall automatically

56

be converted to a CoDev Collaboration Product. Pieris shall reimburse Servier for its share of the Shared Costs paid during the time that such Product was a Servier WW Collaboration Product.

### 3.1.6 <u>Research Funding</u>.

3.1.6.(a) Servier WW Collaboration Products.

(i) Up to [\*\*\*], Servier shall be responsible for all Out-of-Pocket Costs associated with the Development and Manufacture of such Collaboration Product (other than a Pieris Designated CoDev Collaboration Product) starting from the applicable Collaboration Effective Date as outlined in the collaboration budget associated with the current Collaboration Plan for such Collaboration Product (each a "Collaboration Budget"). The initial Collaboration Budgets for the corresponding initial Collaboration Plans are attached to this Agreement as Exhibits 3.1.2(a)1-4 (with the Collaboration Budgets for the Additional Collaboration Products attached as Exhibits 3.1.2(a)5-7 within ninety (90) days of the exercise of the Servier Collaboration Option). Each Party shall be responsible for [\*\*\*], including [\*\*\*], associated with the Development and Manufacture of the Servier WW Collaboration Products, provided that (a) during the Additional Research Collaboration Term (as applicable), Servier shall pay Pieris for its [\*\*\*] a [\*\*\*] of [\*\*\*] (the "Additional Research Collaboration Development Funds"), and such Additional Research Collaboration Development Funds shall be payable to Pieris [\*\*\*], with the [\*\*\*] due upon the Additional Collaboration Effective Date and [\*\*\*], following receipt of invoice from Pieris for the same, and (b) following [\*\*\*], in the event that Servier requests and Pieris agrees to perform activities for Development or Manufacture of a Servier WW Collaboration Product then Servier shall reimburse Pieris for [\*\*\*]. To the extent that there is a Collaboration Renewal Term, the Parties shall discuss in good faith an additional lump sum to be paid to Pieris (the "Collaboration Renewal Development Funds") with respect to such Collaboration Renewal Term. The Parties acknowledge and agree that the Collaboration Renewal Development Funds amount is not intended as a limitation on Pieris' obligation to conduct its activities under the Collaboration Plan or otherwise pursuant to this Agreement.

(ii) Following [\*\*\*] for a given Collaboration Product that constitutes a Servier WW Collaboration Product, Servier shall be responsible for all costs associated with the Development, Manufacture and Commercialization of such Servier WW Collaboration Products.

57

#### 3.1.6.(b) CoDev Collaboration Products.

(i) Up to [\*\*\*] for each Pieris Designated CoDev Collaboration Product, each Party shall be responsible for its Agreed Percentage of the Shared Costs in accordance with the Collaboration Budget associated with such Pieris Designated CoDev Collaboration Product.

(ii) Following [\*\*\*] for a given Collaboration Product, which becomes a CoDev Collaboration Product, the provisions of <u>Section 2.3.2</u> shall apply *mutatis mutandis* with respect to such CoDev Collaboration Product.

(iii) For the avoidance of doubt, subject to <u>Section 3.1.6.(b)(i)</u> and <u>Section 3.1.6.(b)(ii)</u>, and except as otherwise expressly contemplated by this Agreement, each Party shall be responsible for [\*\*\*], associated with the Development and Manufacture of the CoDev Collaboration Products.

#### Section 3.2 Licenses.

### 3.2.1 Research License.

3.2.1.(a) License Grant to Servier. Subject to the terms and conditions set forth herein, on a Collaboration Product-by-Collaboration Product basis, during the applicable Collaboration Term but only up to [\*\*\*] and any Consideration Period for the applicable Collaboration Product, Pieris hereby grants to Servier a co-exclusive (with Pieris), sublicensable (subject to Section 3.2.4 below), personal and non-transferable (except as set forth in Section 13.5), right and license under the Pieris IP solely to perform Servier's obligations under the applicable Collaboration Plan in accordance with this Agreement anywhere in the Pieris Territory and the Servier Territory solely with respect to the Development of such Collaboration Product in the Field; provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this Section 3.2.1.(a) shall be non-exclusive.

3.2.1.(b) <u>License Grant to Pieris</u>. Subject to the terms and conditions set forth herein, on a Collaboration Product-by-Collaboration Product basis, during the applicable Collaboration Term but only up to [\*\*\*] and any Consideration Period for the applicable Collaboration Product, Servier hereby grants to Pieris a co-exclusive (with Servier), sublicensable (subject to <u>Section 3.2.4</u> below), personal and non-transferable

58

(except as set forth in <u>Section 13.5</u>), right and license under the Servier IP solely to perform Pieris' obligations under each Collaboration Plan in accordance with this Agreement anywhere in the Pieris Territory and the Servier Territory solely with respect to the Development of such Collaboration Product in the Field; provided that with respect to any Servier Building Block IP within the Servier IP, the foregoing license under this <u>Section 3.2.1.(b)</u> shall be non-exclusive.

3.2.2 <u>Servier WW Collaboration Products</u>. With respect to each Servier WW Collaboration Product, subject to the terms and conditions of this Agreement, Pieris hereby grants to Servier:

3.2.2.(a) <u>Development License</u>. During the Term following [\*\*\*], an exclusive (even as to Pieris) sublicensable (subject to <u>Section 3.2.4</u> below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Pieris IP to (a) Develop, have Developed (subject to <u>Section 2.3.6</u>) and use such Servier WW Collaboration Product in the Field worldwide, and (b) Manufacture and have Manufactured (subject to <u>Section 2.3.6</u>) the Servier WW Collaboration Product worldwide for the purposes of such Development. The foregoing license shall be exercisable by Servier after [\*\*\*] for such Servier WW Collaboration Product; provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this <u>Section 3.2.2.(a)</u> shall be non-exclusive.

3.2.2.(b) <u>Commercialization License</u>. During the Term following [\*\*\*], an exclusive (even as to Pieris), royalty-bearing, sublicensable (subject to Section 3.2.4 below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Pieris IP to (a) Commercialize the Servier WW Collaboration Product in the Field worldwide and (b) to Manufacture and have Manufactured (subject to <u>Section 2.3.6</u>) the Servier WW Collaboration Product worldwide for the purposes of such Commercialization; provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this <u>Section 3.2.2.(b)</u> shall be non-exclusive.

### 3.2.3 CoDev Collaboration Products.

3.2.3.(a) License Grants to Servier.

(i) <u>Development License</u>. Subject to the terms and conditions set forth herein, Pieris hereby grants to Servier during the Term following [\*\*\*] for a given CoDev Collaboration Product, a co-exclusive (with Pieris), sublicensable (subject to <u>Section 3.2.4</u> below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Pieris IP (1) to Develop

59

and have Developed (subject to <u>Section 3.1.4</u> and <u>Section 2.3.6</u>), and use the CoDev Collaboration Product in the Field anywhere in the Pieris Territory and the Servier Territory, including to perform Servier's obligations under each Collaboration Plan and to undertake Territory Specific Work and Unsponsored Work as permitted herein, and (2) (A) to Manufacture and have Manufactured (subject to <u>Section 3.4</u> and <u>Section 2.3.6</u>), the CoDev Collaboration Product in the Field anywhere in the Pieris Territory and the Servier Territory, and (B) to import, have imported, export and have exported the CoDev Collaboration Product into the Servier Territory and the Pieris Territory, in each case (clause (A) and (B)), solely for such Development; provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this <u>Section 3.2.3.(a)(i)</u> shall be non-exclusive.

(ii) <u>Commercialization License</u>. Subject to the terms and conditions set forth herein during the Term following [\*\*\*] for a given CoDev Collaboration Product, Pieris hereby grants to Servier a royalty-bearing, sublicensable (subject to <u>Section 3.2.4</u> below), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Pieris IP (1) to Commercialize each CoDev Collaboration Product in the Field solely in the Servier Territory, the license granted in this clause (1) to be exclusive (even as to Pieris), and (2) (A) to Manufacture and have Manufactured (subject to <u>Section 3.4</u> and <u>Section 2.3.6</u>), the CoDev Collaboration Product in the Field anywhere in the Pieris Territory and the Servier Territory, and (B) to import, have imported, export and have exported the CoDev Collaboration Product into the Servier Territory, in each case (clause (B) and (B)), solely for such Commercialization, the license granted in this clause (2) to be a co-exclusive (with Pieris); provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license under this <u>Section 3.2.3.(a)(ii)</u> shall be non-exclusive.

#### 3.2.3.(b) License Grants to Pieris.

(i) <u>Development License</u>. Subject to the terms and conditions set forth herein, during the Term following [\*\*\*] for a given CoDev Collaboration Product, Servier hereby grants to Pieris a co-exclusive (with Servier), sublicensable (subject to <u>Section 3.2.4</u>), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Servier IP (1) to Develop and have Developed (subject to <u>Section 3.1.4</u> and <u>Section 2.3.6</u>), and use the CoDev Collaboration Product in the Field anywhere in the Pieris

60

Territory and the Servier Territory, including to perform Pieris' obligations under the Collaboration Plan and to undertake Territory Specific Work and Unsponsored Work as permitted herein, and (2) (a) to Manufacture and have Manufactured (subject to <u>Section 3.4</u> and <u>Section 2.3.6</u>), the CoDev Collaboration Product in the Field anywhere in the Pieris Territory and the Servier Territory, and (b) to import, have imported, export and have exported the CoDev Collaboration Product into the Servier Territory and the Pieris Territory, in each case (clause (a) and (b)), solely for such Development; provided that with respect to any Servier Building Block IP within the Servier IP, the foregoing license under this <u>Section 3.2.3.(b)(i)</u> shall be non-exclusive.

(ii) <u>Commercialization License</u>. Subject to the terms and conditions set forth herein during the Term following [\*\*\*] for a given CoDev Collaboration Product, Servier hereby grants to Pieris a royalty-free, sublicensable (subject to <u>Section 3.2.4</u>), personal and non-transferable (except as set forth in <u>Section 13.5</u>), right and license under the Servier IP (1) to Commercialize the CoDev Collaboration Product in the Field solely in the Pieris Territory, the license granted in this clause (1) to be exclusive (even as to Servier), and (2) (a) to Manufacture and have Manufactured (subject to <u>Section 3.4</u> and <u>Section 2.3.6</u>), the CoDev Collaboration Product anywhere in the Pieris Territory and the Servier Territory, and (b) to import, have imported, export and have exported the CoDev Collaboration Product into the Pieris Territory, in each case (clause (a) and (b)), solely for such Commercialization, the license granted in this clause (2) to be a co-exclusive (with Servier); provided that with respect to any Servier Building Block IP within the Servier IP, the foregoing license under this <u>Section 3.2.3.(b)(ii)</u> shall be non-exclusive.

3.2.4 <u>Sublicense</u>. Servier or Pieris may sublicense (through multiple tiers) all or part of the rights and licenses granted to them under this <u>Section 3.2</u> to an Affiliate or to a Third Party solely in accordance with the terms set forth in <u>Section 5.1.2</u> and <u>Section 5.1.3</u>.

## 3.2.5 Know-How Transfer.

3.2.5.(a) <u>Initial Transfer</u>. Within thirty (30) days following the Effective Date or any other schedule agreed upon by the Parties, each Party (the "*Transferring Party*") shall make available to the other Party the Transferring Party's respective Know-How related to the Collaboration Products that has not been previously made available to such other Party, including the items listed in <u>Exhibit 3.2.5.(a)</u>.

3.2.5.(b) <u>Ongoing Transfer</u>. Subject to <u>Section 3.3.4</u>, when applicable, on a continuing basis throughout the Collaboration Term, the Transferring Party shall promptly make available to the other Party all additional of the Transferring Party's respective Know-How related to the Collaboration Products which comes into existence from time to time, including all information listed in <u>Exhibit 2.1.4.(b)</u> and all Data generated under the Collaboration Plan or Territory Specific Work or under any Unsponsored Work in accordance with <u>Section 3.1.3</u> and all Know-How within the Joint IP which comes into existence from time to time (other than the Know-How related to Manufacturing, which is covered by <u>Section 3.4</u>). Any such documents, reports and data intended to be submitted to Competent Authorities shall be made available in a form and format acceptable by Competent Authorities, e.g., in eCTD-ready format.

3.2.6 <u>Rights of Reference; Use of Data</u>. The provisions of <u>Section 2.1.5</u> shall apply *mutatis mutandis* to the Regulatory Materials and Data in relation to CoDev Collaboration Products.

#### Section 3.3 Governance.

3.3.1 <u>Generally</u>. The governance structure set forth in <u>Section 2.2</u> shall apply *mutatis mutandis* to the Collaboration Products (other than Servier WW Collaboration Products following [\*\*\*]) and the Collaboration Plan, provided that, until [\*\*\*], the JDC shall be replaced by a joint research committee (the "*Joint Research Committee*" or "*JRC*") with the following responsibilities:

(i) Initiating, implementing and overseeing the conduct of any Collaboration Plan;

(ii) preparing updates and proposed amendments to the Collaboration Plan and Collaboration Budget to be submitted to the JSC;

(iii) reviewing, resolving and approving any matters or disputes related to the Development of any Product prior to [\*\*\*];

(iv) establishing a core research and development team to ensure work under the Joint Collaboration Plan is executed efficiently;

62

(v) coordinating the sharing of data under Section 3.3.4; and

(vi) making such determinations as are expressly delegated to it under the terms of this Agreement.

3.3.2 <u>Servier WW Collaboration Products</u>. The governance structure set forth in <u>Section 2.2</u> shall not apply to Servier WW Collaboration Products following [\*\*\*]. Instead, in addition to the data sharing requirements of <u>Section 3.2.5.(b)</u>, Servier shall update Pieris as to the status of the Development and Commercialization of the Servier WW Collaboration Products through a written annual report no later than forty-five (45) days following the end of every Calendar Year outlining Servier's efforts in connection with Development relating to the Servier WW Collaboration Products and giving Pieris notice of material events related to the Development of the Servier WW Collaboration Products, including general timelines with regard to anticipated milestones and communications intended to be achieved within [\*\*\*] following such report. Such reports shall include information on [\*\*\*] that (a) have been [\*\*\*] or (b) are intended to be [\*\*\*]. At [\*\*\*] request, not more than [\*\*\*] per [\*\*\*], [\*\*\*] shall [\*\*\*] [\*\*\*] with respect to Servier WW Collaboration Products, provided that [\*\*\*] shall not be required to do so.

3.3.3 <u>Regulatory</u>. <u>Section 2.3.7(c)</u> with respect to Health Authority Communications shall apply *mutatis mutandis* to the Servier WW Collaboration Products.

3.3.4 <u>Ongoing Information Sharing</u>. Promptly following the Effective Date, the Parties will establish a secure electronic data exchange system through which the Parties shall, subject to any then current obligations or restrictions the sharing Party may have to a Third Party, share on an on-going and regular basis during the Collaboration Term with each other relevant data and information with regard to the Building Blocks used in any Product which could be relevant for the Development of such Product. After the termination of the Collaboration Term, such information shall be limited to any Health Authority Communication with regard to the Building Blocks used in any Product that is being Developed, Manufactured or Commercialized which could be relevant for the Development of such Product.

63

#### Section 3.4 Manufacturing.

#### 3.4.1 Generally.

3.4.1.(a) The Collaboration Plan shall include each Parties responsibilities and activities regarding the Manufacture and supply of the Collaboration Products until [\*\*\*].

3.4.1.(b) [\*\*\*], the principles set forth in <u>Section 2.4</u> shall apply *mutatis mutandis* to CoDev Collaboration Products. Servier shall be solely responsible for the Manufacturing of Servier WW Collaboration Products.

#### Section 3.5 Commercialization.

3.5.1 <u>Servier WW Collaboration Products</u>. Servier shall be solely responsible for and have sole control over all aspects of the Commercialization of the Servier WW Collaboration Products in every country of the world, including planning and implementation, distribution, booking of sales, pricing, reimbursement and costs.

3.5.2 <u>CoDev Collaboration Products</u>. The provisions of <u>Section 2.5</u> shall apply *mutatis mutandis* to the Commercialization of the CoDev Collaboration Products. Subject to the terms of this Agreement, (a) Servier shall be solely responsible for and have sole control of all aspects of the Commercialization of the CoDev Collaboration Products in the Servier Territory, including planning and implementation, distribution, booking of sales, pricing, reimbursement and costs and (b) Pieris shall be solely responsible for and have sole control of all aspects of the Commercialization of the CoDev Collaboration Products in the Pieris shall be solely responsible for and have sole control of all aspects of the Commercialization of the CoDev Collaboration Products in the Pieris Territory, including planning and implementation, distribution, booking of sales, pricing, reimbursement and costs.

### Section 3.6 Payments and Royalties.

#### 3.6.1 <u>Technology Access Fee</u>.

3.6.1.(a) In partial consideration for the rights granted under this Agreement regarding the Collaboration Products under the Initial Research Collaboration, Servier shall pay Pieris a one-time, non-refundable and non-creditable lump sum payment of [\*\*\*] following receipt of the corresponding invoice from Pieris after the Effective Date.

3.6.1.(b) In partial consideration for the rights granted under this Agreement regarding the Servier Collaboration Option and the Additional Collaboration Products under the Additional Research Collaboration, Servier shall pay Pieris a one-time, non-refundable and non-creditable lump sum payment of [\*\*\*] (the "*Servier Collaboration Option Fee*") concurrently with Servier's delivery of the Servier Opt-In Notice to Pieris (pursuant to <u>Section 3.1.1.(c)</u>).

64

### 3.6.2 Development and Regulatory Milestones.

3.6.2.(a) <u>Servier WW Collaboration Products</u>. In partial consideration for the rights granted under this Agreement regarding the Servier WW Collaboration Products, in each case upon initial achievement of the applicable milestone by or on behalf of Servier or its Sublicensees for each Servier WW Collaboration Product, Servier will pay Pieris the corresponding one-time, non-refundable and non-creditable lump sum payment set forth below.

		<b>Payment Amount</b>	
Development Event	<b>1st Indication</b>	2nd Indication	<b>3rd Indication</b>
In vivo PoC or [***]	[***]	[***]	[***]
Start of GLP Tox Studies	[***]	[***]	[***]
Start of Phase 1 Clinical Study	[***]	[***]	[***]
Start of Phase 2a Clinical Study or Phase 1 Clinical			
Study Expansion Cohorts	[***]	[***]	[***]
Start of Pivotal Clinical Study	[***]	[***]	[***]
[***] filing [***]	[***]	[***]	[***]
[***] filing [***]	[***]	[***]	[***]
[***] filing [***]	[***]	[***]	[***]
Marketing Approval [***]	[***]	[***]	[***]
Marketing Approval [***]	[***]	[***]	[***]
Marketing Approval [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Notwithstanding the above, with respect to each Marketing Approval (centralized procedure) in Europe and Marketing Approval in the United States milestone, if any such approval is granted but conditional upon the completion of an additional Clinical Study in the applicable country, in lieu of paying the amount corresponding to such approval, Servier shall pay [\*\*\*] of such amount upon issuance of the conditional approval and [\*\*\*] of such amount upon issuance of the confirmatory approval.

65

3.6.2.(b) <u>CoDev Collaboration Products</u>. In partial consideration for the rights granted under this Agreement regarding the CoDev Collaboration Products, in each case upon initial achievement of the applicable milestone by or on behalf of Servier or Servier's respective Affiliates or Sublicensees for each CoDev Collaboration Product, Servier will pay Pieris the corresponding one-time, non-refundable and non-creditable lump sum payment set forth below.

	<b>Payment Amount</b>	
Development Event	<b>1st Indication</b>	2nd Indication
In vivo PoC or [***]	[***]	[***]
Start of GLP Tox Studies	[***]	[***]
Start of Phase 1 Clinical Study	[***]	[***]
Start of Phase 2a Clinical Study or Phase 1 Clinical Study		
Expansion Cohorts	[***]	[***]
Start of Pivotal Clinical Study	[***]	[***]
[***] filing [***]	[***]	[***]
[***] filing [***]	[***]	[***]
[***] filing [***]	[***]	[***]
Marketing Approval [***]	[***]	[***]
Marketing Approval [***]	[***]	[***]
Marketing Approval [***]	[***]	[***]
[***]	[***]	[***]

Notwithstanding the above, with respect to each Marketing Approval (centralized procedure) in Europe milestone, if the approval is granted but conditional upon the completion of an additional Clinical Study, in lieu of paying the amount corresponding to such approval, Servier will pay [\*\*\*] of such amount upon issuance of the conditional approval and [\*\*\*] of such amount upon issuance of the confirmatory approval.

66

Payment

3.6.2.(c) Skipped Development and Regulatory Milestones. If any of the above development and regulatory milestones are skipped (i.e. a later milestone payment is payable before an earlier milestone payment in the same jurisdiction, if applicable), or if Regulatory Approval is achieved in any jurisdiction with respect to a Servier WW Collaboration Product (under Section 3.6.2.(a)) or CoDev Collaboration Product (under Section 3.6.2.(b) without all of the preceding milestone payments applicable to such Product in such jurisdiction, if applicable, having been achieved, then the skipped milestone(s) will be deemed to have been achieved upon the achievement of the subsequent milestone or upon Regulatory Approval, as applicable. If the MAA in Europe is filed through another procedure than the centralized procedure, the Parties will discuss in good faith the opportunity to adjust the milestones.

CONFIDENTIAL TREATMENT REQUESTED

3.6.3 <u>Sales Milestones</u>. As partial consideration for the rights granted hereunder regarding the Servier WW Collaboration Products, Servier shall make the non-refundable, non-creditable, one-time sales milestone payments to Pieris based upon achievement of the following worldwide annual Calendar Year cumulative Royalty Bearing Net Sales for each Servier WW Collaboration Product.

Annual Calendar Year - Royalty Bearing Net Sales
Threshold
[\*\*\*]
[\*\*\*]
[\*\*\*]
[\*\*\*]

For clarity, one or more of the above sales milestones may be achieved during the same Calendar Year.

### 3.6.4 Royalties.

3.6.4.(a) <u>Servier WW Collaboration Products</u>. As partial consideration for the rights granted hereunder regarding the Servier WW Collaboration Products, during the Royalty Term Servier shall pay Pieris royalties equal to the following percentages of Royalty Bearing Net Sales of the each of the Servier WW Collaboration Products in a Calendar Year in the Servier Territory, subject to adjustment as set forth in <u>Section 4.1</u> (*"Servier WW Collaboration Product Royalties"*):

Annual Calendar Year Royalty Bearing Net Sales	<b>Royalty Rates owed by Servier</b>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

67

#### Confidential

## CONFIDENTIAL TREATMENT REQUESTED

3.6.4.(b) <u>CoDev Collaboration Products</u>. As partial consideration for the rights granted hereunder regarding the CoDev Collaboration Products, during the Royalty Term Servier shall pay Pieris royalties equal to the following percentages of Royalty Bearing Net Sales of each of the CoDev Collaboration Products in a Calendar Year in the Servier Territory, subject to adjustment as set forth in <u>Section 4.1</u> (*"CoDev Collaboration Product Royalties"*):

Annual Calendar Year Royalty Bearing Net Sales	<b>Royalty Rates owed by Servier</b>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

## ARTICLE 4 ROYALTY ADJUSTMENT; PAYMENT TERMS; RECONCILIATION

#### Section 4.1 Royalty Adjustments.

4.1.1 <u>Biosimilar Drug Competition</u>. Notwithstanding the foregoing, subject to <u>Section 4.1.2.(d)</u>, if in any Calendar Quarter total sales of any Biosimilar(s) of a Product in any country reaches more than [\*\*\*] in [\*\*\*] of the [\*\*\*] of the applicable Product and the Biosimilar(s) in such country, then (a) the Royalties payable to Pieris for such Product in such country shall be reduced by [\*\*\*] of the amount otherwise payable hereunder and (b) beginning [\*\*\*] years from the First Commercial Sale of the Product in such country and thereafter, no further Royalties shall be due for such Product in such country. Notwithstanding the foregoing, in the event of Biosimilar sales that are later enjoined by a court or otherwise halted (such as on the basis of patent or regulatory exclusivity), then subsequent royalties shall be restored to the level otherwise contemplated under this Agreement.

## 4.1.2 Third Party Licenses.

4.1.2.(a) If it is reasonably necessary for Servier (including as evidenced by an opinion of internationally recognized outside counsel) to license one or more Patent Rights from one or more Third Parties in order to Develop, Manufacture (other than manufacturing processes), Commercialize or use the drug substance of any Product (due to, for example, the polypeptide sequence or targets of such Product but excluding, for example, formulation Patents or Manufacturing process Patents), whether directly or through any Affiliate or Sublicensee, in the

68

Servier Territory, then Servier may negotiate and obtain a license under such Patent Right(s) (each such Third Party license referred to herein as a "*Third Party License*"). Without prejudice to the provisions of <u>Section 11.2</u> and <u>Section 12.2</u>, if any payments are due to a Third Party pursuant to a Third Party License or in the context of proceedings brought by any Third Party alleging that one or more Patent Rights of such Third Party is infringed by the Development, Manufacture (other than manufacturing processes), Commercialization or use of the drug substance of any Product in the Field under this Agreement, then subject to Section <u>4.1.2.(d)</u>, Servier may deduct [\*\*\*] of such payment(s) from the Royalties associated to such Product otherwise payable under <u>Section 2.6.6</u> and <u>Section 3.6.4</u> but in no event shall Royalties be reduced by greater than [\*\*\*] under this <u>Section 4.1.2.(a)</u>.

4.1.2.(b) Notwithstanding the foregoing, to the extent (i) a Thirty Party License or (ii) a license with any other Third Party contracted to provide cell line generation services for the production of a Product, is required in order for Pieris and Servier to Develop, Manufacture, Commercialize or use the Lead Product or a CoDev Product in the Pieris Territory and in the Servier Territory, then Pieris and Servier shall jointly negotiate such license and each shall be responsible for its Agreed Percentage of all upfront fees, maintenance fees and milestone payments (as applicable) and each Party shall be responsible for royalties in its Territory that are required thereunder. Notwithstanding the foregoing, all payments (including upfronts, maintenance, milestones or other payments) or royalties owed to [\*\*\*] or any other Third Party contracted to provide cell line generation services for the production of a Servier WW Collaboration Product shall be borne solely by Servier. Servier shall not have the right to reduce the Royalties associated with such Product in the event the Parties obtain a Third Party License or license with [\*\*\*] or other Third Party contracted to provide cell line generation services, under this <u>Section 4.1.2.(b)</u>.

4.1.2.(c) For avoidance of doubt, <u>Sections 4.1.2.(a)</u> and <u>4.1.2.(b)</u> do not limit either Party's right to obtain any Third Party License as it may deem necessary or useful.

4.1.2.(d) <u>Maximum Deduction</u>. Notwithstanding anything to the contrary herein, under no circumstances shall the combined effect of all reductions to the Royalties permitted under <u>Sections 4.1.1</u> and <u>4.1.2.(a)</u>, on a country-by-country and Product-by-Product basis, reduce the effective Royalties payable by Servier to Pieris under this Agreement for any [\*\*\*] below [\*\*\*] of the Royalties that would otherwise be payable pursuant to <u>Section 2.6.6</u> and <u>Section 3.6.4</u>, as applicable, for such Product in such country.

69

#### 4.1.3 Building Block Contributions.

4.1.3.(a) The Parties agree that Pieris is responsible for contributing the Building Blocks that target [\*\*\*] and [\*\*\*] solely for the Lead Product and the Building Blocks that Target [\*\*\*], as well as all Anticalin Building Blocks solely for the Collaboration Products ("*Pieris' Contribution*"). The Parties further agree that Servier is responsible for contributing the Building Blocks that target [\*\*\*] and [\*\*\*] solely for the Collaboration Products ("*Servier's Contribution*").

4.1.3.(b) [\*\*\*] shall be [\*\*\*] for all [\*\*\*] or [\*\*\*] and [\*\*\*] with respect to the particular [\*\*\*] for the corresponding Product, in each case as identified in (and in accordance with) the first sentence of Section 4.1.3.(a) above. [\*\*\*] shall be [\*\*\*] for [\*\*\*] or [\*\*\*] and [\*\*\*] with respect to the particular [\*\*\*] for the corresponding Product, in each case as identified in (and in accordance with) the second sentence of Section 4.1.3.(a) above.

4.1.3.(c) For avoidance of doubt and by way of example: (i) if Servier's Building Block that Targets [\*\*\*] is used in [\*\*\*], then [\*\*\*] for all [\*\*\*] to [\*\*\*] to [\*\*\*] in connection with the Development and Commercialization of the Lead Product that contains such Building Block; (ii) if Pieris' Building Block that Targets [\*\*\*] is used in [\*\*\*], then [\*\*\*] shall [\*\*\*] to [\*\*\*] to [\*\*\*] in connection with the Development and Commercialization of such Collaboration Product that contains such Building Block; or (iii) if [\*\*\*] a [\*\*\*] with a [\*\*\*] to [\*\*\*] for one or more [\*\*\*], then [\*\*\*] shall [\*\*\*] for all [\*\*\*] to such [\*\*\*] in connection with the Development and Commercialization of such Collaboration Product that contains such Building Block; or (iii) if [\*\*\*] a [\*\*\*] with a [\*\*\*] to [\*\*\*] for one or more [\*\*\*], then [\*\*\*] shall [\*\*\*] for all [\*\*\*] to such [\*\*\*] in connection with the Development and Commercialization of such Collaboration Product that contains such Building Block. For further avoidance of doubt, this <u>Section 4.1.3</u> is only intended to address initial responsibility of the Parties to contribute the particular Building Blocks for the corresponding Products as outlined in <u>Sections 4.1.3.(a) and 4.1.3.(b)</u> above and does not relate to, and is not intended to address. Third Party licenses or any other licenses necessary or useful in connection with the Development, Manufacture or Commercialization of the Products.

#### Section 4.2 Reports; Reconciliation.

4.2.1 <u>Sales Payment Reports and Royalty Payments</u>. After the First Commercial Sale by the Seller of a Product requiring the payments due to Pieris pursuant to <u>Section 2.6.5</u>, <u>Section 2.6.6</u>, <u>Section 3.6.3</u> or <u>Section 3.6.4</u> and ending, on a Product-by-Product basis, following the last to expire Royalty Term with respect to such Product, Servier shall send to Pieris within [\*\*\*] after the end of each Calendar Quarter (a) a written report which shall state, for the previous Calendar Quarter, on a country-by-country and Product-by-Product basis, the description of each Product sold, the corresponding amount of gross sales of

70

Products, an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales and the calculation of any milestones fees and Royalties due, including any reductions made in accordance with this Agreement, as well as the exchange rate for such country, and (b) payment (in Euros) of all royalty payments due to Pieris hereunder for such Calendar Quarter.

#### 4.2.2 Shared Cost Reconciliation.

4.2.2.(a) Within [\*\*\*] after the end of each Calendar Quarter, each Party will provide the other Party with a detailed, itemized accounting of Shared Costs actually incurred by such Party in its performance of the Joint Development Plan or the Collaboration Plan, as applicable, during such Calendar Quarter (the "*Shared Cost Report*").

4.2.2.(b) With respect to each Calendar Quarter, no later than the later of (i) [\*\*\*] following the end of such Calendar Quarter and (ii) [\*\*\*] following Pieris' receipt of the Shared Cost Report, the Parties shall calculate the reconciliation amount to be paid by each Party (the "*Reconciliation Report*").

4.2.2.(c) Within [\*\*\*] after the Parties' agreement as to the Reconciliation Report by Pieris, as applicable, the Party having paid more than its Agreed Percentage of the actual Shared Costs (on a cumulative basis) shall deliver to the other Party an invoice for such excess amount.

4.2.2.(d) <u>Overruns</u>. Each Party will promptly notify the other Party upon becoming aware that the anticipated Shared Costs for a given Product to be incurred by such Party for a given Calendar Quarter will be in excess of the applicable Development Budget or Collaboration Budget for that Calendar Quarter for such Product. Unless otherwise agreed by the Parties in writing in advance through the Committees, Shared Costs reported by a Party in a Shared Cost Report in excess of [\*\*\*] of the amounts budgeted on a Product-by-Product basis to be incurred by or on behalf of such Party for its activities for such Product in such Calendar Quarter in the then-current applicable Development Budget or Collaboration Budget, respectively, shall be borne by the Party that incurred such costs.

#### Section 4.3 Payment Terms.

4.3.1 <u>Generally</u>. All payments made by a Payor Party pursuant to <u>Section 2.6</u> and <u>Section 3.6</u> shall be made in immediately available funds by wire transfer to such bank and account the Payee Party as may be designated from time to time by Payor Party. Except as otherwise set forth herein, all other payments due under this Agreement will be paid within [\*\*\*] following receipt of an invoice requesting such payment. All invoices provided to the Payor Party hereunder should include Payee Party's bank details, the contact name for issue resolution and will be marked for the attention of the Alliance Manager.

71

4.3.2 <u>Late Payments</u>. Interest shall accrue on any late payment of fees owed to the Payee Party not made on the date such payment is due, at an annual interest rate equal to the lesser of (a) the Euribor one month with respect to payments in Euros plus [\*\*\*] or (b) the highest rate permissible by Law, with such interest accruing from the date the payment was originally due to Payee Party.

4.3.3 <u>Taxes and Withholding</u>. All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this <u>Section 4.3.3</u>. The Parties agree to cooperate with one another and use reasonable efforts to minimize under applicable Law obligations for any and all income or other taxes required by applicable Law to be withheld or deducted from any of the royalty and other payments made by or on behalf of a Party hereunder ("*Withholding Taxes*"). The applicable paying Party under this Agreement (the "*Payor Party*") shall, if required by applicable Law, deduct from any amounts that it is required to pay to the recipient Party hereunder (the "*Payee Party*") an amount equal to such Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for the Payee Party's account and, if available, evidence of such payment shall be secured and sent to Payee Party within [\*\*\*] of such payment. The Payor Party shall, at the Payee Party's sole cost and expense, as mutually agreed by the Parties, do all such lawful acts and things and sign all such lawful deeds and documents as the Payee Party may reasonably request to enable the Payor Party hereunder without deducting any Withholding Taxes.

4.3.4 <u>Conversions</u>. With respect to amounts required to be converted into another currency for calculation of the Net Sales amount, the milestones and the Royalty payments, such amount shall be converted using a rate of exchange which corresponds to the average quarterly rate published by the European Central Bank as used by Payor Party for conversion between the relative currencies for its reporting period in its books and records that are maintained in accordance with Accounting Standards, as applicable, for its external reporting.

### Section 4.4 Record and Audit.

4.4.1 <u>Generally</u>. Each Party shall keep complete, true and accurate books of account and records for the purpose of determining the amounts payable under this Agreement. Such books and records shall be kept at the principal place of business of each Party, as the case may be, for at least [\*\*\*] years (or such longer period as required by applicable Law) following the end of the Calendar Year to which they pertain. Each Party (the "*Audited Party*") shall make such account and records available, on reasonable notice sent by the other Party (the "*Auditing Party*"), for inspection during normal business hours, with not less than [\*\*\*]

72

advance written notice, by an independent certified public accounting firm nominated by such and reasonably acceptable for the Audited Party, for the purpose of verifying the accuracy of any statement or report given by the Audited Party and to verify the accuracy of the payments due hereunder for any Calendar Year. Such auditor shall advise the Parties simultaneously promptly upon its completion of its audit whether or not the payments due hereunder have been accurately recorded, calculated and reported, and, if not, then the amount of such discrepancy. A Party's financial records with respect to a given period of time shall only be subject to one (1) audit per Calendar Year except in the case of willful misconduct or fraud. The Auditing Party's right to perform an audit pertaining to any Calendar Year shall expire [\*\*\*] years after the end of such Calendar Year. The auditor shall be required to keep confidential all information learned during any such inspection, and to disclose to the Auditing Party shall be responsible for the auditor's costs, unless the auditor certifies that there was a variation or error of underpayment or overpayment exceeding [\*\*\*] of the amount stated for any period covered by the inspection, then all reasonable costs relating to the inspection for such period. If such accounting firm correctly identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be paid/refunded promptly but in any event within forty-five (45) days of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties.

### **ARTICLE 5 RIGHT OF FIRST NEGOTIATION; DROPPED PRODUCTS**

### Section 5.1 Right of First Negotiation.

#### 5.1.1 Servier Right of First Negotiation.

5.1.1.(a) Subject to the obligations set forth in this <u>Section 5.1.1</u>, following, in each case, the applicable [\*\*\*] for such Product, Pieris may enter into a Partnering Agreement for the Lead Product or a CoDev Collaboration Product (each, a "*Pieris ROFN Product*") in the Pieris Territory to a Third Party (the "*Pieris Partner*").

5.1.1.(b) In the event that Pieris desires to enter into a Partnering Agreement with regard to a Pieris ROFN Product in accordance with this <u>Section 5.1.1</u> or receives a written offer from a Third Party to enter into negotiations for a Partnering Agreement, Pieris shall, in each case, provide Servier written notice prior to commencing such processes or responding to such offer, as applicable ("*Pieris ROFN Notice*"). The Pieris ROFN Notice shall identify the Product and rights (including geographical territories) that Pieris wishes to offer to a Third Party. If, within [\*\*\*] following receipt of the Pieris ROFN Notice, Servier notifies Pieris of its interest to license such Pieris ROFN Product, Pieris and Servier shall enter

#### 73

into good faith negotiations on an exclusive basis for [\*\*\*] of [\*\*\*] to attempt to negotiate the financial terms for acquisition of such rights and, if the Parties are able to reach mutual agreement on such terms with such [\*\*\*] period, shall further negotiate in good faith for a period of [\*\*\*] an amendment to this Agreement to incorporate such Pieris ROFN Product (*"Pieris ROFN Product Amendment"*). If (a) Servier does not provide such written notice within [\*\*\*] or (b) the Parties fail to reach agreement for such Pieris ROFN Product Agreement for such Pieris ROFN Product within [\*\*\*] or (c) the Parties fail execute a Pieris ROFN Product Agreement for such Pieris ROFN Product within [\*\*\*] following mutual agreement on the financial and key terms, then Pieris shall be free to enter into a Partnering Agreement with a Third Party on terms that, in the sole but reasonable discretion of Pieris, are no more favorable (when taken as a whole) to such Third Party than those offered to Servier and otherwise shall have no further obligation to Servier. Notwithstanding the foregoing, nothing in this <u>Section 5.1.1</u> shall in any way restrict, limit or prohibit or be deemed to restrict, limit or prohibit Pieris from soliciting, negotiating, facilitating, executing or undergoing a Change of Control.

#### 5.1.2 Pieris Right of First Negotiation.

5.1.2.(a) Subject to the obligations set forth in this <u>Section 5.1.2</u>, following, in each case, the applicable [\*\*\*] for such Product and prior to a Change of Control of Pieris contemplated by <u>Section 5.1.2.(c)</u> below, Servier may enter into a Partnering Agreement with regard to the [\*\*\*] (each a "*Servier ROFN Product*") in [\*\*\*] with a Third Party (the "*Servier Partner*"). For the avoidance of doubt, Servier shall be free to enter into a Partnering Agreement outside of [\*\*\*] with any Third Party, subject to the other terms of this Agreement including the obligations set forth in <u>Section 5.1.2.(c)</u> and <u>Section 5.1.3</u>.

5.1.2.(b) In the event that Servier desires to enter into a Partnering Agreement with regard to a Servier ROFN Product in accordance with this <u>Section 5.1.2</u> or receives a written offer from a Third Party to enter into negotiations for a Partnering Agreement, Servier shall, in each case, provide Pieris written notice prior to commencing such processes or responding to such offer, as applicable ("*Servier ROFN Notice*"). The Servier ROFN Notice shall identify the Servier ROFN Product and rights (including geographical territories) that Servier wishes to offer to a Third Party. If, within [\*\*\*] following receipt of the Servier ROFN Notice, Pieris notifies Servier of its interest to license such Servier ROFN Product, Pieris and Servier shall enter into good faith negotiations on an exclusive basis for a period of [\*\*\*] to attempt to negotiate the financial terms for acquisition of such rights and, if the Parties are able to reach mutual agreement on such terms with such [\*\*\*] period, shall further negotiate in good faith for a period of [\*\*\*] an agreement ("*Servier ROFN Product* 

74

*Agreement*"). If (a) Pieris does not provide such written notice within [\*\*\*] or (b) the Parties fail to reach agreement on the financial terms within the subsequent [\*\*\*] period or (c) the Parties fail execute a Servier ROFN Product Agreement for such Servier ROFN Product within [\*\*\*] following mutual agreement on the financial and key terms, then Servier shall be free to enter into a Partnering Agreement with a Third Party on terms that, in the sole but reasonable discretion of Servier, are no more favorable (when taken as a whole) to such Third Party than those offered to Servier and otherwise shall have no further obligation to Pieris. Notwithstanding the foregoing, nothing in this <u>Section 5.1.2</u> shall in any way restrict, limit or prohibit or be deemed to restrict, limit or prohibit Servier from soliciting, negotiating, facilitating, executing or undergoing a Change of Control.

5.1.2.(c) Effect of Change of Control. For the avoidance of doubt, in the event that Pieris undergoes a Change of Control where the [\*\*\*] is a [\*\*\*], then Pieris' right as set forth in this Section 5.1.2 shall immediately cease and Servier shall have the right to sell, transfer or sublicense its rights under this Agreement to Third Parties, subject to the terms of this Agreement including the obligations set forth in Section 5.1.3. For purposes of this Agreement, the term "[\*\*\*]" shall mean a [\*\*\*] in the [\*\*\*] as established by [\*\*\*] in the [\*\*\*] prior to the Change of Control.

#### 5.1.3 Partnering Agreement Obligations & Sublicense Survival.

5.1.3.(a) Servier's and Pieris' right to enter into a Partnering Agreement shall be conditioned upon, such Party's obligation to promptly inform the other of the Partnering Agreement and shall ensure that the Partnering Agreement is consistent with and fully implements the relevant provisions of this Agreement and each Party's rights under this Agreement. Each Sublicensee shall be obligated to fulfill the funding and governance obligations of the sublicensing Party set forth in this Agreement. Each Partnering Agreement shall protect the original licensing Party's ("*Licensor*") rights and interests in such Party's intellectual property to at least the same extent as this Agreement, including without limitation containing provisions for the benefit of the Licensor substantially similar in language and scope to the license provisions set forth in <u>Section 2.1</u> and <u>Section 3.2</u>, as applicable, the ownership provisions in <u>Section 7.1</u>, as applicable, the confidentiality provisions set forth in <u>ARTICLE 8</u>, as applicable, and the publication provisions set forth in <u>ARTICLE 9</u>, as applicable, of this Agreement. The Party entering the Partnering Agreement agrees to cause or otherwise ensure that each Servier Partner or Pieris Partner, as applicable, comply with the terms and conditions of the Partnering Agreement, and shall be deemed to be an act or omission of such Servier Partner or Pieris Partner.

75

## 5.1.3.(b) Sublicense Survival.

(i) With respect to any (sub)license agreement(s) entered into with a Sublicensee by either Party (the "Sublicensing Party") in effect as of the date at which termination or expiration of this Agreement becomes effective and the Sublicensee's rights under such Sublicense, to the extent that the Sublicensee is in good standing with respect to the Sublicense and was not itself the cause of the termination of this Agreement, the other Party (the "Non-Sublicensing Party") will negotiate in good faith a direct license with the Sublicensee under the following terms and conditions (provided that such Sublicensee does not, within thirty (30) days following the termination or expiration of this Agreement, provide written notice to the Non-Sublicensing Party of Sublicensee's election to terminate the Sublicense): (1) the Parties shall negotiate such direct license in good faith in order to execute a direct license within sixty (60) days of the termination or expiration of this Agreement, and (3) such direct license to the Sublicensee by the Non-Sublicensing Party shall not place any additional obligations (including but not limited to representations, warranties, or liabilities) on the Non-Sublicensing Party beyond its obligations under this Agreement without the prior written consent of the Non-Sublicensing Party.

(ii) In the event that a Sublicense is terminated or rejected by or on behalf of the Sublicensing Party under the applicable provisions of any bankruptcy laws, then the Non-Sublicensing Party hereby grants to Sublicensee a direct license in accordance with the following terms and conditions (provided that such Sublicensee does not, within thirty (30) days following the termination or rejection of the Sublicense, provide written notice to the Non-Sublicensing Party of Sublicensee's election to terminate the Sublicense): (1) the Parties shall negotiate the terms of such direct license in good faith in order to execute that license within sixty (60) days of the termination or rejection of the Sublicense, (2) such direct license shall have the same scope, payment and financial terms and non-financial terms as this Agreement, and (3) such direct license to the Sublicensee by the Non-Sublicensing Party shall not place any additional obligations (including but not limited to representations, warranties, or liabilities) on the Non-Sublicensing Party beyond its obligations under this Agreement without the prior written consent of the Non-Sublicensing Party.

76

#### Section 5.2 Dropped Products.

5.2.1 <u>Generally</u>. Each Party has the right to elect to cease its Development or Commercialization (including Manufacture thereof for purposes of such Development or Commercialization, as applicable) of a Product to the extent permitted under this <u>Section 5.2</u> (such Product, a "*Dropped Product*"), and the following terms and conditions shall apply, provided that (a) Servier shall not drop the Lead Product during the [\*\*\*] and (b) Pieris shall not drop the Lead Product [\*\*\*], provided that nothing in the foregoing (a) or (b) shall restrict or otherwise limit a Party from exercising its termination rights pursuant to <u>Section 12.2</u>.

5.2.1.(a) <u>Notice</u>. The Party that is dropping the Product (in accordance with this <u>Section 5.2</u>) (the "*Dropping Party*") shall provide the other Party written notice of such intention along with the date thereof ("*Dropped Product Notice*") no less than [\*\*\*] prior to ceasing any such activity ("*Dropped Product Notice Period*", the last day of the Dropped Product Notice Period becoming the "*Drop Date*"). During the Dropped Product Notice Period, and without limiting the other requirements of this <u>Section 5.2</u> (including <u>Section 12.3.1.(e)</u>), the Party that is dropping the Product shall continue to fulfill all its obligations under this Agreement with respect to such Product.

5.2.1.(b) <u>Effect of Dropped Product by Single Party</u>. In addition to the specific effects set forth in <u>Section 5.2.1.(c)</u>, in the event Servier drops a Product in accordance with <u>Section 5.2.1.(a)</u>, the provisions of <u>Section 12.3.1</u> shall apply, effective upon the Drop Date.

### 5.2.1.(c) Specific Effects Following a Dropped Product.

(i) Servier Dropped Product.

1. In the event Servier drops a Product pursuant to this <u>Section 5.2.1</u> and the Drop Date for such Dropped Product occurs prior to the completion of the first Phase 1 Clinical Study Expansion Cohort or Phase 2a Clinical Study, in consideration of the rights set forth in <u>Section 12.3.1</u>, Pieris shall pay Servier a percentage of Pieris', its Affiliates' and Sublicensees' (as such term is applied *mutatis mutandis* to Pieris) net sales (calculated as the Net Sales applied *mutatis mutandis*) for such Dropped Product equal to: (x) if such Dropped Product was the Lead Product or a CoDev Collaboration Product, [\*\*\*] and (y) if such Dropped Product was a Servier WW Collaboration Product, [\*\*\*]. For purposes of this <u>Section 5.2.1.(c)</u>, "completion" means database lock.

#### 77

2. In the event Servier drops a Product pursuant to this <u>Section 5.2.1</u> and the Drop Date for such Dropped Product occurs after the completion of the first Phase 1 Clinical Study Expansion Cohort or Phase 2a Clinical Study, in consideration of the rights set forth in <u>Section 12.3.1</u>, Pieris shall pay Servier a percentage of Pieris', its Affiliates' and Sublicensees' (as such term is applied *mutatis mutandis* to Pieris) net sales (calculated as the Net Sales applied *mutatis mutandis*) for such Dropped Product equal to: (x) if such Dropped Product was the Lead Product or a CoDev Collaboration Product, [\*\*\*] and (y) if such Dropped Product was a Servier WW Collaboration Product, [\*\*\*].

3. In the event Servier drops a Product at any time pursuant to this <u>Section 5.2.1</u>, effective as of the Drop Date for such Dropped Product, Servier and its Affiliates shall be released from their non-compete undertaking pursuant to <u>Section 6.2</u> with respect to such Dropped Product.

(ii) <u>Pieris Dropped Product</u>. In the event Pieris drops a Product at any time pursuant to this Section 5.2.1.(c), effective as of the Drop Date for such Dropped Product:

1. The Servier Territory for such Dropped Product shall be extended to include all countries in the world and the Net Sales of the Dropped Product shall be computed on a worldwide basis;

2. All licenses and sublicenses granted by Pieris to Servier hereunder with respect to such Dropped Product shall become exclusive (even as to Pieris), provided that with respect to any Pieris Building Block IP within the Pieris IP, the foregoing license shall remain non-exclusive;

3. All licenses and sublicenses granted by Servier to Pieris hereunder with respect to such Dropped Product shall terminate;

4. If such Dropped Product is a CoDev Collaboration Product, then the Royalties payable to Pieris under <u>Section 3.6.4.(a)</u> shall apply on a worldwide basis, provided that the royalty rates set forth in <u>Section 3.6.4.(a)</u> shall be increased

78

by (A) [\*\*\*] if the Drop Date for such Dropped Product occurs prior to [\*\*\*], or (B) [\*\*\*] if the Drop Date for such Dropped Product occurs after the [\*\*\*] for such Product;

5. If such Dropped Product is a CoDev Collaboration Product, the development and sales milestones under <u>Sections 3.6.2.(a)</u> and <u>3.6.3</u> as applicable to a Servier WW Collaboration Product shall apply with respect to such Dropped Product;

6. If such Dropped Product is the Lead Product, the payment terms in Exhibit 5.2.1.(c) (ii) shall apply;

7. For the avoidance of doubt, if such Dropped Product is the Lead Product or a CoDev Collaboration Product, it shall be treated as a Servier WW Collaboration Product except as otherwise set forth herein including that Servier's diligence obligations under <u>Section 6.1</u> will continue to apply with respect to the Servier Territory outside of the United States but shall not apply to the United States;

8. The provisions of Sections 12.3.1(b), (c), and (e)–(j) shall apply *mutatis mutandis* as of the applicable Drop Date, with any reference in these Sections to (a) the effective date of termination being replaced by the Drop Date, and (b) a terminated Product being replaced by the Dropped Product; and

9. Pieris' and its Affiliates' non-compete undertaking pursuant to <u>Section 6.2</u> with respect to such Dropped Product shall remain in force.

5.2.1.(d) Effect of Product Dropped by Both Parties. In the event both Parties mutually agree to drop a Product in accordance with Section 5.2.1.(a), the terms of Section 12.3.2 shall apply as of the date for which the Parties mutually agree to drop the Product.

79

### **ARTICLE 6 DILIGENCE; EXCLUSIVITY**

## Section 6.1 Diligence Obligation.

6.1.1 <u>Generally</u>. Pieris and Servier shall use Commercially Reasonable Efforts to perform their respective activities contemplated by this Agreement, as may be agreed upon in any subsequent written agreements with respect to the subject matter hereof, including but not limited to any activities under the then-current Joint Development Plan, Collaboration Plan and any other plans or tasks approved by a Committee.

6.1.1.(a) <u>Servier</u>. Servier shall use Commercially Reasonable Efforts to Develop and Commercialize each Product in the Field in the Servier Territory. In particular, Servier shall use Commercially Reasonable Efforts to Commercialize each Product in [\*\*\*].

6.1.1.(b) <u>Pieris</u>. Pieris shall use Commercially Reasonable Efforts to Develop and Commercialize each of the Lead Product and the CoDev Collaboration Products in the Field in the Pieris Territory.

#### Section 6.2 Non-Compete.

#### 6.2.1 Non-Compete.

6.2.1.(a) During the Term, each Party and its Affiliates covenants not to Develop, Manufacture or Commercialize, itself or with its Affiliate or any Third Party, any Competing Product anywhere in the world except as expressly permitted under this Agreement.

6.2.1.(b) If Pieris or Servier (whether alone or with a Third Party) wish to Develop, Manufacture or Commercialize a product, which product is not a Product or a Competing Product, and if such product binds to and modulates all of the same therapeutically relevant targets (as further described in <u>Section 1.69</u>) as a Product, but such product also [\*\*\*] and [\*\*\*], then such Party will be permitted to so Develop, Manufacture or Commercialize such product; provided that such Party notifies the JSC in advance of commencing such activity and otherwise complies with the terms and conditions of this Agreement, including without limitation, the requirements of <u>ARTICLE 8</u> and <u>Section 10.4</u>. The Parties may, each in their respective sole discretion, agree to include such product under the Research Collaboration or this Agreement as a Pieris Designated CoDev Collaboration Product for all purposes under this Agreement at terms, including up-front financial terms, to be mutually agreed by the Parties in good faith.

#### 80

6.2.2 Effect of Acquisition. Notwithstanding Section 6.2.1, each Party acknowledges that the other Party (the "Concerned Party") may be acquired or merge with a Third Party or acquire a Third Party during the Term of this Agreement (such transaction, an "Acquisition Transaction", and such Third Party, the "Acquiror" or "Acquiree"). In such event, if the Acquiror or Acquiree (or a Third Party that is an Affiliate of such Acquiror or Acquiree prior to and following the date of such Acquisition Transaction) was Developing, Manufacturing or Commercializing one or more Competing Product(s) prior to the closing of such Acquisition Transaction (each an "Acquired Competing Product"), subject to the Concerned Party's compliance with this Section 6.2.2, such Concerned Party shall be deemed not to be in breach of Section 6.2.1:

6.2.2.(a) if and to the extent permitted by <u>Section 5.2.1</u>, it drops the Product corresponding to the Acquired Competing Product in accordance with <u>Section 5.2.1</u> within [\*\*\*] after the closing of the Acquisition Transaction;

6.2.2.(b) if it Divests to a Third Party or permanently discontinues the Development and Commercialization of the Acquired Competing Product within [\*\*\*] after the closing of the Acquisition Transaction;

6.2.2.(c) if it contributes the Acquired Competing Product to the collaboration between the Parties on terms and conditions to be negotiated in good faith and that are mutually acceptable to the Parties, each in its respective sole discretion, with such agreement, if any, to be reflected in an amendment to this Agreement or a separate agreement to be entered into by and between the Parties within [\*\*\*] after the closing of the Acquisition Transaction; or

6.2.2.(d) if it requires that, the Acquiror (or Acquiree) and its Affiliates existing as of the date of the Acquisition Transaction (excluding the Concerned Party and its Affiliates) continue to Develop (including Manufacture thereof solely for such Development purposes) such Acquired Competing Product without the participation or use of assets (including employees) owned or employed by the Concerned Party prior to the Acquisition Transaction, provided that, in the event the Concerned Party elects to proceed in accordance with this <u>Section 6.2.2.(d)</u>, no later than [\*\*\*] following the completion of the [\*\*\*] or [\*\*\*] for [\*\*\*], and in any event and under all circumstances prior to any Commercialization of such Acquired Competing Product anywhere in the world, the Concerned Party shall elect, and shall complete, one of the options set forth in the foregoing <u>Sections 6.2.2.(a)</u>, 6.2.2.(b), and 6.2.2.(c) above with respect either to

81

the Competing Acquired Product (i.e., if the Concerned Party elects <u>Section 6.2.2.(b)</u> or 6.2.2.(c)) or the Product corresponding thereto (i.e., if the Concerned Party elects <u>Section 6.2.2.(a)</u>), as applicable. For clarity, any Commercialization of the Acquired Competing Product anywhere in the world (except as expressly contemplated by <u>Section 6.2.2</u>) shall be deemed a breach of this <u>Section 6.2</u> by the Concerned Party. For avoidance of doubt, Divestiture of the Acquired Competing Product in accordance with <u>Section 6.2.2.(b)</u> shall not constitute Commercialization of the Acquired for purposes of this <u>Section 6.2.2.(d)</u>. In the event that the Concerned Party drops the Product corresponding to the Acquired Competing Product in accordance with <u>Section 6.2.2.(f)</u>, the Acquirer (or Acquiree) and its <u>Section 6.2.2.(d)</u>, the Concerned Party shall require that, subject to <u>Section 6.2.2.(f)</u>, the Acquirer (or Acquiree) and its Affiliates existing as of the date of the Acquisition Transaction (excluding the Concerned Party and its Affiliates) continue to Develop and Commercialize (including Manufacture thereof for such purposes) such Acquired Competing Product without the participation or use of assets (including employees) owned or employed by the Concerned Party prior to the Acquisition Transaction. For avoidance of doubt, if Pieris is the Concerned Party and drops or has dropped the Product corresponding to the Acquired Competing Product, then Pieris' non-compete obligations referenced in <u>Section 5.2.1.(c)</u> shall not apply to such Product.

6.2.2.(e) Notwithstanding the foregoing, if a Party is acquired by an Acquiror having a Competing Product (i) of the Lead Product or a CoDev Product that such Party has entirely out-licensed to a Third Party or (ii) if such Party is Pieris, of a Servier WW Collaboration Product, such Acquiror or Acquiree or its Affiliates prior to the Acquisition Transaction may in lieu of (a) to (d) above, elect to continue to Develop and Commercialize (including Manufacture thereof for such purposes) such Acquired Competing Product without the participation or use of assets (including employees) owned or employed by the Acquiror or Acquiree prior to the Acquisition Transaction or resulting from this Agreement.

6.2.2.(f) For purposes of this <u>Section 6.2.2</u>:

(i) The term "*Divest*" or "*Divestiture*" means, with respect to an Acquired Competing Product, the sale, exclusive (even with respect to a Party and its Affiliates) license, or other delegation, assignment or transfer by a Party or its Affiliates of all of their respective Development and Commercialization rights or obligations with respect to such compound or product to a Third Party without the retention or reservation of any commercialization interest or participation rights (other than solely an

82

economic interest or the right to enforce customary terms and conditions contained in the relevant agreements effectuating such Divestiture, including rights of access and review in connection therewith).

(ii) With respect to <u>Sections 6.2.2.(a)</u> through <u>6.2.2.(e)</u>, the acquired or acquiring Party and its Affiliates (including the Acquirer or Acquiree and their respective Affiliates) will adopt reasonable procedures (which include appropriate administrative, physical and technical safeguards, including underlying operating system and network security controls and other firewalls) to prevent the disclosure of (1) all Confidential Information of the other Party, (2) all Pieris IP, Servier IP and Joint IP, and (3) all other information (including Know-How) with respect to the Development, Manufacture or Commercialization of Products (including any Joint Development Plans and Collaboration Plans), including any structures of any such item and any Data generated in connection with activities hereunder (collectively, the "*Sensitive Information*") beyond such acquired or acquiring Party's and its Affiliates' and Sublicensees' or subcontractors' employees, agents or independent contractors who actively work under this Agreement or any Party Supply Agreement and who do not work on any Acquired Competing Program, which procedures will include reasonable restrictions on the scope of any Sensitive Information required to be provided by the other Party. For clarity, the foregoing will not apply to any Sensitive Information that is not treated as Confidential Information hereunder. Pending the election of <u>Sections 6.2.2.(a) to 6.2.2.(d)</u>, or as long as <u>Section 6.2.2.(e)</u> applies, the Non-Concerned Party shall be released from its governance and reporting obligations to the Concerned Party with respect to the Development and Commercialization of the Product (other than pursuant to <u>Section 4.2.1</u>).

# ARTICLE 7 INTELLECTUAL PROPERTY; OWNERSHIP AND ENFORCEMENT

#### Section 7.1 Ownership; Joint IP.

7.1.1 <u>Background IP</u>. As between the Parties, all Know-How and Intellectual Property Rights Controlled by a Party prior to the Effective Date or developed separate and apart from this Agreement, shall be deemed owned by the Party Controlling such Know-How and Intellectual Property Rights.

#### 7.1.2 Building Block IP; Pieris Platform Improvement IP.

7.1.2.(a) <u>Building Blocks</u>. A Party's Building Blocks, together with the corresponding Building Block IP (including improvements) for such Building Block in-licensed by a Party or generated solely by employees, agents, or independent contractors of either Party or its Affiliates in the course of performing activities under this Agreement, shall be solely owned by the Party which initially contributed or in-licensed such Building Block, subject to any rights and licenses granted herein. For clarity, the foregoing ownership shall be afforded regardless of whether such Building Block would otherwise constitute Joint IP under this Agreement.

83

7.1.2.(b) <u>Pieris Platform Improvement IP</u>. Pieris Platform Improvement IP shall be solely owned by Pieris. Servier, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to Pieris all its right, title and interest in and to any Pieris Platform Improvement IP. Servier will cooperate, and will cause its and its Affiliates' respective employees, agents and contractors to cooperate, with Pieris to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership. For clarity, no right is granted to Servier under this Agreement with respect to the Pieris Platform Improvement IP.

7.1.3 <u>Foreground IP</u>. Except for Joint IP and as set forth in <u>Section 7.1.2</u>, any invention conceived and reduced to practice, or Know-How generated, solely by employees, agents, or independent contractors of a Party or its Affiliates in the course of performing activities under this Agreement, together with all Intellectual Property Rights therein, shall be owned by such Party. All Joint IP shall be owned jointly by the Parties and each Party shall have an equal and undivided right therein.

7.1.4 <u>Right to Exploit Joint IP</u>. Subject to and except as otherwise provided in this Agreement including with respect to the licenses granted to Servier under <u>Section 2.1.1.(a)</u>, <u>Section 3.2.2</u> and <u>Section 3.2.3.(a)</u> and the licenses granted to Pieris under <u>Section 2.1.2</u> and <u>Section 3.2.3.(b)</u> with respect to the Products, the non-compete obligation in <u>Section 6.2</u>, and the allocation of ownership of certain rights under <u>Section 7.1.2</u>, each Party shall have the right to freely sell, assign, license, encumber and otherwise exploit Joint IP without consent of or notice or accounting to the other Party.

#### Section 7.2 <u>Patent Prosecution</u>.

7.2.1 <u>General</u>. Except as otherwise set forth in this <u>Section 7.2</u>, each Party will have the sole responsibility, at such Party's sole discretion and sole expense, to prepare, file, prosecute and maintain, in such Party's name, all Patent Rights owned or Controlled by such Party, including without limitation, that Pieris shall have such rights with respect to all Patent Rights within the Pieris Platform IP and Pieris Platform IP. Notwithstanding the foregoing, Pieris shall inform Servier of any material impairment of the Pieris Platform IP in Europe.

7.2.2 <u>Lead Product.</u> Pieris shall be responsible for the filing, prosecution and maintenance of the Product Specific Patents Covering the Lead Product throughout the world. All costs and expenses of filing, prosecuting and

84

maintaining such Patent Rights shall be shared in accordance with the Agreed Percentage until national stage, and then, each Party shall bear the costs of prosecuting and maintaining such Patent Rights in its respective Territory. Pieris shall provide Servier with the opportunity to review and comment on any and all such filing and prosecution efforts regarding such Patent Rights. Servier shall provide Pieris reasonable assistance in such efforts; provided that Pieris shall have final control over such filing and prosecution efforts for such Patents after reasonably considering Servier's comments in good faith, provided that Pieris shall follow Servier's instruction with respect to the opt-out procedure of the Unitary Patent System. In case of disagreement regarding the filing, maintenance or prosecution of such Patents, the issue will be discussed in the JIPC and may be escalated to the JSC and JEC in the event of continued disagreement. If Pieris determines to abandon or not maintain any such Patent Rights, Pieris shall provide Servier with prior written notice of such determination at least [\*\*\*] before any loss of rights would occur with respect to such Patent Rights at its sole discretion and expense.

#### 7.2.3 Collaboration Product Patents.

7.2.3.(a) Pieris Designated CoDev Collaboration Products and CoDev Collaboration Products. Pieris and Servier shall collaborate to prepare the patent application(s) for the Product Specific Patents Covering the Pieris Designated CoDev Collaboration Products or the CoDev Collaboration Products subject to both Parties' review and approval. Servier shall be responsible for the filing of any priority and subsequent PCT applications and, upon national entry, Servier shall be responsible for the filing, maintenance of such Patents in its Territory and Pieris shall be responsible for the filing, maintenance of such Patents in its Territory and expenses of filing, prosecuting and maintaining such Patent Rights shall be shared in accordance with the Agreed Percentage until national stage, and then, each Party shall bear the costs of prosecuting and maintaining such Patent Rights in its respective Territory. Each Party shall provide the other Party with the opportunity to review and comment on any and all such prosecution efforts regarding such Patent Rights, and each Party shall provide the other Party reasonable assistance in such efforts; provided that each Party shall have final control over such prosecution efforts after reasonably considering the other Party's comments in its Territory. If a Party determines to abandon or not maintain any such Patent Rights in its Territory, this Party shall provide the other Party with prior written notice of such determination at least [\*\*\*] before any loss of rights would occur with respect to such Patent Rights in any applicable patent office or patent granting authority and the other Party shall have the right to assume the right to prosecute and maintain such Patent Rights at its sole discretion and expense.

85

7.2.3.(b) Servier WW Collaboration Products. Pieris and Servier shall collaborate to prepare the patent application for the Product Specific Patents Covering Servier WW Collaboration Products subject to both Parties' review and approval (provided that in the event of a disagreement, Servier shall decide except for (i) any sections of an application that contains any Pieris Confidential Information and (ii) for the first Patent filing and the PCT filing). Servier shall be responsible for the filing, prosecution and maintenance of the Patent Rights Covering the Servier WW Collaboration Products throughout the world. All costs and expenses of filing, prosecuting and maintaining such Patent Rights shall be borne by Servier. Servier shall provide Pieris with the opportunity to review and comment on any and all such prosecution efforts regarding such Patent Rights, and Pieris shall provide Servier reasonable assistance in such efforts; provided that Servier shall have final control over such prosecution efforts after reasonably considering Pieris' comments. If Servier determines to abandon or not maintain any such Patent Rights, Servier shall provide Pieris with prior written notice of such determination at least [\*\*\*] before any loss of rights would occur with respect to such Patent Rights in any applicable patent office or patent granting authority and Pieris shall have the right to assume the right to prosecute and maintain such Patent Rights at its sole discretion and expense.

7.2.4 <u>Other Joint Patents</u>. To the extent any Joint Patent is not a Product Specific Patent, or if any Joint Patent or Product Specific Patent Covers more than one Product, then the Parties shall discuss in good faith the sharing of responsibilities and costs in connection with the filing, prosecution and maintenance of such IP. In the absence of agreement, <u>Section 7.2.3.(a)</u> shall apply *mutatis mutandis* to any such Patents.

7.2.5 <u>Building Block Patents.</u> Each Party will have the sole responsibility, at such Party's sole discretion and sole expense, to prepare, file, prosecute, maintain or abandon, in such Party's name, all Patent Rights within such Party's Building Block IP. Each Party will, through the JIPC, consult with the other Party regarding its strategy for the prosecution and maintenance of all such Patent Rights, and shall consider in good faith the other Party's comments regarding the same. Each Party will provide the other copies of all substantive filings and documents related to the prosecution and maintenance of such Patents Rights. Each Party will provide the other sufficient opportunity to review and comment on any prosecution and maintenance activity regarding such Patent Rights. For the avoidance of doubt, each Party shall furnish to the other Party its anticipated filing dates for any such Patents Rights as are relevant to a Product in a timely matter to reasonably enable coordination between the Parties regarding the same.

86

The controlling Party will consider in good faith timely comments from the non-controlling Party thereon.

7.2.6 Each Party will use Commercially Reasonable Efforts to make available to the other its authorized attorneys, agents or representatives, or such of its employees as are reasonably necessary to assist the other Party in exercising its rights described under this <u>Section 7.2</u>. Each Party will sign, or will use Commercially Reasonable Efforts to have signed, all legal documents as are reasonably necessary to prosecute and maintain Patents in accordance with this <u>Section 7.2</u>. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts described above in this <u>Section 7.2</u>, including providing any necessary powers of attorney, oaths, declarations, assignments, and executing any other required documents or instruments for such prosecution.

7.2.7 Notwithstanding this <u>ARTICLE 7</u>, Servier shall not take any action in the prosecution of the Product Specific Patents or Joint Patents pursuant to this Agreement that would have a material adverse impact on any Patent Rights within the Pieris Building Block IP, the Pieris Platform IP, or the Pieris Platform Improvement IP, and Pieris shall not take any action in the prosecution of the Product Specific Patents or Joint Patents pursuant to this Agreement that would have a material adverse impact on any Patent Rights within the Servier Building Block IP.

**Section 7.3 Common Interest Disclosures**. With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property and/or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Joint Development Plan, Collaboration Plan, or Development of any Product, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the Joint Development Plan, Collaboration Plan, or Development of any Product. Accordingly, the Parties agree that all such information and materials obtained by Pieris and Servier from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

87

#### Section 7.4 Patent Term Extensions.

7.4.1 Servier will have the sole right but not the obligation to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights, for any Product Specific Patents Covering the Collaboration Products in the Servier Territory. For the Lead Product, Pieris agrees to execute any authorization or instruments, make any filings, or take such further actions as may be requested by Servier to implement and obtain any patent term extension, supplementary protection certificates or similar extension of rights, for any Product Specific Patents Covering the Lead Product in the Servier Territory, at Servier's expense. Servier will have the sole right but not the obligation to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights, using any Servier Building Block IP. At Servier's request, Pieris shall reasonably consider applying for such an extension with respect to any Pieris Building Block IP, Pieris Platform IP or Pieris Platform Improvement IP.

7.4.2 Pieris will have the sole right but not the obligation to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights, for any Product Specific Patents Covering the Lead Product and Covering the Collaboration Products in the Pieris Territory. Pieris will have the sole right but not the obligation to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights, using any Pieris Building Block IP, Pieris Platform IP or Pieris Platform IP. At Pieris' request, Servier shall reasonably consider applying for such an extension with respect to any Servier Building Block IP.

#### Section 7.5 Intellectual Property Litigation.

7.5.1 <u>Third Party IP Claims</u>. For the purposes of this <u>Section 7.5</u>, "*Third Party IP Claim*" shall mean, with regard to any given Patent Right or Product:

7.5.1.(a) any suspected or threatened infringement of any such Patent Right by a Third Party in the Field (including any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions or of any declaratory judgment, or similar action alleging the invalidity, unenforceability or non-infringement of any such Patent Rights or any administrative challenge to any such Patent Rights under Chapters 31 and 32 of Title 35, USC or similar provisions in other jurisdictions alleging the unpatentability of any Intellectual Property);

7.5.1.(b) any claim by a Third Party that the exercise of the rights granted hereunder under the Patent Rights infringes any Intellectual Property Rights (excluding Trademarks) of a Third Party in the Field;

7.5.1.(c) any claim by a Third Party of alleged patent infringement with respect to the Development, Manufacture or Commercialization of any Product in the Field;

88

7.5.1.(d) any suspected or actual misappropriation of the Know-How required to be transferred to a Party as set forth in this Agreement in the Field.

7.5.2 <u>Cooperation</u>. Each Party will promptly notify the other Party in writing of any Third Party IP Claim and of any known or suspected infringement or unauthorized use or misappropriation by a Third Party of any Pieris Patent Rights or Servier Patent Rights in the Field (such suspected infringement or unauthorized use or misappropriation, "*Competing Infringement*") of which such Party becomes aware. The notifying Party will provide the other Party with all evidence available to it supporting its belief that there is Competing Infringement.

## 7.5.3 Defense.

7.5.3.(a) Each Party shall be responsible for any claim by a Third Party that its activities related to this Agreement, including the Development, Manufacture or Commercialization of a Product, infringe any Patent Rights of a Third Party in its Territory, such as a claim under Sections 7.5.1.(b) or 7.5.1.(c) (such Party, the "**Defending Party**"). The Defending Party shall be responsible for legal fees and any monetary damages levied in connection with any such action.

7.5.3.(b) As between the Parties, the Party controlling the prosecution and maintenance of any Patent under Section 7.2 will have the right (but not the obligation), at its sole discretion and expense, to defend against a declaratory judgment action or other action challenging any such Patent. If the Party controlling such prosecution and maintenance of Patents under Section 7.2 does not confirm it will defend such Patent under this Section 7.5.3.(b) within [\*\*\*] (or such shorter period of time as is required under the applicable Law in the United States or any other country in the Territory to not waive any statutory rights), or elects not to continue any such defense (in which case it will promptly provide notice thereof to the other Party), then the other Party will have the right (but not the obligation), at its sole discretion, to defend any such Patent.

7.5.3.(c) For avoidance of a doubt, the Defending Party or the Party defending an action under <u>Section 7.5.3.(b)</u> shall have the right to obtain assistance from the other Party as set forth in <u>Section 7.5.5.</u>

#### 7.5.4 Enforcement.

7.5.4.(a) Servier shall have the sole and exclusive right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Competitive Infringement in the Servier Territory of any Servier Patent Rights, Servier Know-How, Joint Patent, Joint Know-How, or Product Specific Patents. Such measures may include (a) initiating or

89

prosecuting an infringement, misappropriation or other appropriate suit or action (each an "*Infringement Action*") in the Servier Territory, or (b) granting adequate rights and licenses to any Third Party necessary to render continued Competitive Infringement in the Servier Territory non-infringing. Pieris will consider in good faith any request from Servier to initiate an Infringement Action in the Servier Territory against any Third Party with respect to such Competitive Infringement of any Pieris Building Block Patent Rights or Patent Rights within the Pieris Platform IP or Pieris Platform Improvement IP; provided, however, that Pieris shall not be required to initiate any such Infringement Action or permit Servier to initiate any such Infringement Action with respect to any Pieris Building Block Patent Rights or Patent Rights within the Pieris Platform IP or Pieris Platform Improvement IP. Notwithstanding the foregoing, if Servier does not inform Pieris that it intends to either initiate such an Infringement Action or grant adequate rights and licenses to such Third Party within [\*\*\*] after Servier's receipt of a notice of infringement (or sooner if any deadlines require action prior to such [\*\*\*], then Pieris will have the second right, but not the obligation, to initiate such Infringement Action, but solely with respect to any Joint Patent, Joint Know-How, Product Specific Patents, or Patent Rights within the Pieris IP, Pieris Platform IP or Pieris Platform Improvement IP.

7.5.4.(b) Pieris shall have the sole and exclusive right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Competitive Infringement in the Pieris Territory of any Pieris Patent Rights, Pieris Know-How, Joint Patent, Joint Know-How, or Product Specific Patents. Such measures may include (a) initiating or prosecuting an Infringement Action in the Pieris Territory, or (b) granting adequate rights and licenses to any Third Party necessary to render continued Competitive Infringement in the Pieris Territory non-infringing. Servier will consider in good faith any request from Pieris to initiate an Infringement Action in the Pieris Territory against any Third Party with respect to such Competitive Infringement of any Servier Building Block Patent Rights; provided, however, that Servier shall not be required to initiate any such Infringement Action or permit Pieris to initiate any such Infringement Action with respect to any Servier Building Block Patent Rights. In the event that Pieris does not wish to initiate or discontinues such an Infringement Action, Servier shall not have the right to initial such Infringement Action.

7.5.5 <u>Cooperation and Settlement</u>. During the pendency of such action with respect to any Third Party IP Claim, at the other Party's request, the Party responsible for defending or enforcing any such action (the "*Responsible Party*") shall provide the other Party with all information reasonably requested regarding the status of such action (subject to the other Party entering into a common interest agreement if requested by the

90

Responsible Party, and without disclosing any information that would compromise attorney-client privilege or similar privileges). All materials provided by the Responsible Party to the other Party shall be treated as the Responsible Party's Confidential Information. In any action or defense initiated by the Responsible Party, the other Party shall be entitled to, and if legally required shall, join the action so long as the Responsible Party retains at all times the sole right to direct and control the action (including the choice of its own counsel). The other Party is entitled to be independently represented by counsel of its choice, at its expense. When either Party is bringing or defending an action with respect to any Third Party IP Claim, then (a) upon request by the Responsible Party, the other Party will assist in the defense against or enforcement of such action at the other Party's costs, including if required or desirable to bring, maintain or prove damages in such action, furnishing a power of attorney, furnishing documents and information, cooperating in discovery, providing access to witnesses (including inventors) and executing all necessary documents as such Party may request, and (b) neither Party shall settle, consent to judgment or otherwise voluntarily dispose of the suit or action without the prior written consent of the other Party, which consent shall not be unreasonably delayed, conditioned, or withheld if such settlement, consent to judgment or other voluntary disposition does not impose any liability on the other Party (other than liability that is fully satisfied by the settling Party on behalf of the other Party) and does not impose any restrictions on the other Party.

7.5.6 <u>Allocation of Proceeds</u>. The proceeds recovered by a Party from any enforcement action described in <u>Section 7.5.4</u> (including any licensing revenues) shall be first allocated to the reimbursement of the reasonable attorneys' fees and out-of-pocket costs incurred by the Party who exercises its enforcement rights with respect to the Third Party IP Claims under this <u>Section 7.5.6</u> and then to cover such costs and expenses of the other Party, provided that if such other Party has not elected to join the action but has been required to do so by the enforcing Party, the enforcing Party shall pay the reasonable out-of-pocket costs of the other Party. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared between the Parties, with the Party who exercises its enforcement rights under this <u>Section 7.5.6</u> and recovers damages retaining [\*\*\*] and the other Party retaining [\*\*\*] of such funds. If such recovery exceeds the amount required to cover all such costs and expenses of both Parties, the excess proceeds shall be split and with the enforcing Party retaining [\*\*\*] of such excess proceeds. Notwithstanding the foregoing, with respect to CoDev Collaboration Products or the Lead Product, where Pieris is the enforcing Party with respect to any action in the United States, Pieris shall retain all remaining funds resulting from such action.

91

#### Section 7.6 Trademarks.

7.6.1 <u>Product Trademarks</u>. Each Party shall select one or more product trademarks (including backup trademarks) for the Products for use by such Party in its Respective Territory (including backup trademarks) (the "*Product Trademarks*") in line with the agreed upon Global Branding Strategy. Each Party (or its local Affiliates, as appropriate) shall own and retain all rights to Product Trademarks, together with all goodwill associated therewith, worldwide, and all e-brands, trade dress, service marks, domain names, designs and copyrights for the Product in its respective Territory.

7.6.2 Responsibility.

7.6.2.(a) Servier shall be responsible for filing, registering, maintaining and defending Product Trademarks in the Servier Territory at Servier's expense and in its own name. Subject to any Global Branding Strategy, Servier may, at its own discretion, select for the Product Trademark which was already filed or registered in Servier's portfolio. Servier shall have the right to affix any logo or trade name of its choice on the Product in the Servier Territory.

7.6.2.(b) Pieris shall be responsible for filing, registering, maintaining and defending Product Trademarks in the Pieris Territory at Pieris' expense and in its own name. Subject to any Global Branding Strategy, Pieris may, at its own discretion, select for the Product Trademark which was already filed or registered in Pieris' portfolio. Pieris shall have the right to affix any logo or trade name of its choice on the Product in the Pieris Territory.

7.6.2.(c) If the Parties agree that Pieris will use in its Territory Product Trademarks selected by Servier for the Lead Product or any the CoDev Products, Servier shall file and maintain such Product Trademarks in Pieris Territory in consultation with Pieris (including, as appropriate, through the JIPC), at Pieris' costs, and shall grant to Pieris an exclusive license with the right to sublicense, to the Product Trademarks in connection with the Development, Manufacturing and Commercialization of the Lead Product or the CoDev Products in the Pieris Territory, as applicable.

7.6.3 <u>Domain Names</u>. The Parties may also separately select domain names including or close to a Product Trademark owned by such Party. Such Party shall be responsible for filing and registering such domain names at such Party's expense and in its own name.

7.6.4 <u>Ownership; Rights</u>. Subject to the remainder of this <u>Section 7.6</u>, neither Party shall have any interest, title or right in any of the Trademarks used by a Party or other trade dress, logos, trade names and designs. Neither Party shall directly or indirectly seek through judicial or administrative process, to invalidate, oppose or challenge the validity, enforceability or scope of any Trademarks or other trade dress,

92

logos, trade names and designs used by the other Party in connection with any Products. During the Term of this Agreement and thereafter, the Parties undertake not to take any actions and not to assist in any such actions to acquire any property rights in and to the Trademarks, trade dress, logos, trade names, and designs used in connection with the Products by the other Party, in particular not to register nor attempt to register in its name any trademark, trade name, trade or designs, identical or similar to the Trademarks, trade dress, logos, trade names, and designs used in connection with the Products by the other Party shall not register nor use directly or indirectly any domain name including a name identical to or similar to the Trademarks or trade names used by the other Party in connection with any Product.

7.6.5 <u>Approval Right.</u> Any and all use by each Party of the Trademarks or and any trade dress, logos, trade names, and designs used in connection with the Products by the other Party shall be subject to the other Party's prior express written approval.

7.6.6 <u>Monitoring</u>. Each Party shall maintain vigilance and shall promptly notify the other Party of any infringements or possible infringements of the Trademarks, trade dress, logos, trade names, and designs used in connection with the Products of which it becomes aware.

7.6.7 <u>Use of Name</u>. The Party in charge of a Clinical Study shall ensure that its name can be freely used and register it. The other Party shall be allowed to make reference to this Clinical Study and to use its registered name for the promotion and the commercialization of the Lead Product or the CoDev Collaboration Product in its Territory. Servier may use the Anticalin<sup>®</sup> trademark or name in connection with Clinical Studies and Development activities for the Products (but not in connection with Commercialization).

93

### **ARTICLE 8 CONFIDENTIAL INFORMATION**

**Section 8.1 Confidentiality.** Except to the extent expressly authorized by this Agreement or agreed in writing by the Parties, during the Term and for a period of five (5) years after its termination or expiration, the Parties agree that the Receiving Party shall: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement; provided that the foregoing obligations will apply to any Confidential Information that constitutes a trade secret pursuant to Chapter I, Article 2 of EU Directive 2016/943 or Article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("*ADPIC Treaty*") and has been identified or reasonably understood to be such by the disclosing Party for so long as such Confidential Information is afforded trade secret pursuant to Chapter I, Article 39 of the ADPIC Treaty.

**Section 8.2** Authorized Disclosure. The Receiving Party shall only be entitled to disclose, on a need to know basis for the purpose of the performance of the Agreement, Confidential Information of the Disclosing Party to its directors, employees, Affiliates, consultants, advisors, Sublicensees, inventors or successors in interest (in the event of a merger, acquisition or Change of Control of the Receiving Party) (or potential Sublicensees, inventors or successors in interest solely to the extent necessary for the evaluation of a potential sublicense or investment or merger, acquisition or Change of Control), or Third Party subcontractors (collectively the "*Authorized Recipients*"); provided that such Authorized Recipients are bound by confidentiality and restricted use obligations or professional standards of confidentiality with respect to such Confidential Information that are at least as stringent as those set forth in this Agreement. The Receiving Party will use diligent efforts to cause its Authorized Recipients to comply with such confidentiality and restricted use obligations. The Receiving Party shall be responsible towards the Disclosing Party for any breach by its Authorized Recipients any such confidentiality and restricted use obligations.

#### Section 8.3 Disclosure to Third Parties.

8.3.1 <u>Right to Disclose</u>. Notwithstanding the foregoing provisions of <u>Section 8.1</u>, each Party may disclose Confidential Information of the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary:

8.3.1.(a) to Competent Authorities (a) to the extent desirable to obtain or maintain Regulatory Approvals for any Product within the Party's respective Territory, and (b) in order to respond to inquiries, requests or investigations relating to Products or this Agreement;

94

8.3.1.(b) in connection with filing or prosecuting Patent Rights or trademark rights, in each case relating to Products, as permitted by this Agreement;

8.3.1.(c) in connection with prosecuting or defending litigation as permitted by this Agreement;

8.3.1.(d) to the counterparty of the Pieris Background Agreements, or the Servier Background Contract to which such Receiving Party is the contracting Party in order to comply therewith;

8.3.1.(e) subject to the provisions of <u>ARTICLE 9</u>, in connection with or included in scientific presentations and publications relating to Products, including abstracts, posters, journal articles and the like, and posting results of and other information about Clinical Studies to clincialtrials.gov or similar websites; and

8.3.1.(f) to the extent necessary in order to enforce its rights under this Agreement.

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to this <u>Section 8.3</u>, then the former Party shall, if available, use commercially reasonable effort to obtain a protective order, confidential treatment or other similar measures narrowing the scope of such use and public or other disclosure of such Confidential Information and otherwise take such measures to ensure confidential treatment of such information as is reasonably required. For clarification, any such limited disclosure shall not cause any such information to cease to be Confidential Information.

#### Section 8.4 Excluded Information.

8.4.1 <u>Excluded Information</u>. Notwithstanding <u>Section 8.1</u>, the Confidential Information of the Disclosing Party shall not include information or materials that:

8.4.1.(a) at the time of disclosure to, or acquisition by, the Receiving Party or its Affiliates is generally available to the public, or after the time of disclosure or acquisition is generally available to the public through no wrongful act or omission of the Receiving Party or its Authorized Recipients in breach of this Agreement;

8.4.1.(b) was in the lawful possession and at the free disposal (not subject to a duty of confidentiality or restricted use obligations) of the Receiving Party prior to disclosure by the Disclosing Party, as evidenced by written records then in the possession of the Receiving Party;

95

8.4.1.(c) is rightfully made available to the Receiving Party by Third Parties not bound by confidentiality or restricted use obligations; or

8.4.1.(d) is independently discovered or developed by the Receiving Party without access to or use of the Confidential Information of the Disclosing Party, as evidenced by written records then in the possession of the Receiving Party.

**Section 8.5** Legally Required Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information of the Disclosing Party that is disclosed by the Receiving Party in order to comply with the requirements of applicable Law (and only to the extent so required), provided that the Receiving Party shall to the extent possible give reasonable advance written notice of such disclosure to the Disclosing Party and will cooperate with the Disclosing Party in protecting against any such disclosure and/or obtaining a protective order, confidential treatment or other similar measures narrowing the scope of such use and public or other disclosure of such Confidential Information and otherwise taking such measures to ensure confidential treatment of such information as is reasonably required. Any such compelled disclosure will be to the minimum extent permissible as required by applicable Law. For clarification, any such limited disclosure shall not cause any such information to cease to be Confidential Information.

#### Section 8.6 Terms of this Agreement.

8.6.1 The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by <u>Section 8.3</u> (other than <u>8.3.1.(e)</u>) and <u>Section 8.5</u>. Each Party will also be permitted to disclose the terms of this Agreement (including the exhibits hereto), in each case under appropriate confidentiality provisions, on a need to know basis, to a Party's (and its Affiliates') existing investors and to any bona fide potential or future permitted acquirer or assignee, investment banker, investor, licensee, Sublicensee, collaborator or lender with whom a Party (or its Affiliates) has entered into good faith negotiations regarding a proposed transaction, provided that (a) the disclosing Party agrees to redact information that it reasonably believes is not relevant to the proposed transaction, and (b) the financial terms of this Agreement may be disclosed to any of the foregoing named Persons only after negotiations with such Person have progressed so that such Party reasonably believes that a transaction is reasonably expected to occur.

8.6.2 <u>Securities Filings</u>. Each Party acknowledges and agrees that the other Party may submit this Agreement (including for clarity, the Exhibits and Schedules hereto) to the United States Securities and Exchange Commission (the "*SEC*") or any other securities exchange and if a Party does submit this Agreement to the SEC or any other securities exchange, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by

96

applicable Law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC or any other securities exchange or otherwise to comply with applicable Law, and (a) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, (b) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (c) such Party has given the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by applicable Law. Notwithstanding anything to the contrary herein, it is hereby understood and agreed that if a Party is seeking to make a disclosure as set forth in this Section 8.6.2, and the other Party provides comments within the respective time periods or constraints specified herein or within the respective notice, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith consider incorporating such comments.

**Section 8.7** Agreement Termination. Upon termination of this Agreement, at the Disclosing Party's request, the Receiving Party will return or destroy all documents or other media containing Confidential Information of the Disclosing Party, provided however that the Receiving Party may retain one (1) copy for archival and compliance purposes, and as required by applicable Law.

**Section 8.8 Remedies.** The Parties agree that money damages may not be an adequate remedy if this <u>ARTICLE 8</u> is breached and, therefore, either Party may, in addition to any other legal or equitable remedies, seek an injunction or other equitable relief against such breach or threatened breach without the necessity of posting any bond or surety.

#### **ARTICLE 9 PUBLICATIONS**

**Section 9.1 Restrictions.** Without limiting <u>ARTICLE 8</u> and subject to the other provisions of this <u>ARTICLE 9</u>, neither Party shall (a) make any publication or disclosure of Data generated pursuant to the Joint Development Plan or the Collaboration Plan or by or on behalf of the other Party without complying with this <u>ARTICLE 9</u> or otherwise obtaining the prior written approval of the other Party or (b) use the name of the other Party in any publicity or advertising without the prior written consent of the other Party.

**Section 9.2** Scientific Papers, Abstracts and Posters. The provisions below apply to preclinical and clinical Data with respect to CoDev Products and the Lead Product, but not to Servier WW Collaboration Products, for which Pieris shall not be entitled to make any publication and Servier shall have entire flexibility to make or not make publications. Pre-clinical and clinical data with respect to CoDev Collaboration Products and the Lead Product may be presented at scientific meetings on a regular basis in accordance with the provisions below. The JDC or JRC, as applicable, shall discuss attendance at conferences and work in good faith to coordinate messaging and any presentations or posters at such events.

97

9.2.1 Scientific Papers. Each Party through the JSC or its designee shall provide to the other, prior to submission of a draft of any articles and papers, including primary reports of Data, pooled analyses, theses, dissertations and review papers concerning the Product which have been prepared by or on behalf of such Party or under the Joint Development Plan or the Collaboration Plan (each a "Scientific Paper") to be published in medical and scientific journals and similar publications ("Medical Journals"). Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have [\*\*\*] Business Days to notify the sending Party of its observations and suggestions with respect thereto (it being understood that, during such [\*\*\*]Business Day period, no submission for publication thereof shall take place) and the Parties shall discuss these observations and suggestions. The receiving Party shall have the right to require modifications to such Scientific Paper for patent reasons, trade secret reasons or business reasons, and the sending Party shall remove all Confidential Information of the receiving Party if so requested by the receiving Party. The Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any Patent. The other Party may in good faith require that the publication be suspended for a period of time not exceeding [\*\*\*] if a Patent may be filed using the Data or Know-How covered in the proposed publication, which period could be extended to an additional [\*\*\*] period with respect to Data or Know-How useful to enrich the patent applications provided that in the event such additional delay is requested, (a) such requesting Party must reasonably demonstrate the need for such extension by providing the other Party with a detailed rationale and explanation therefor along with a reasonably detailed work plan as to how such delay and experiments may improve patentability and (b) the Parties will discuss in good faith the scope and duration of any such extended delay (not to exceed such [\*\*\*]). Neither Party will publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of any final Scientific Paper accepted by a Medical Journal, not less than [\*\*\*] Business Days prior to the planned publication thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines). To enable free exchange of copyrighted material between the Parties, each Party agrees that it has or shall (i) obtain and maintain, at its own expense, an Annual Copyright License or equivalent license from the Copyright Clearance Center and (ii) list the other Party as a collaborator in an agreement with the Copyright Clearance Center.

9.2.2 <u>Abstracts and Posters</u>. If a Party intends to present findings with respect to any Product at symposia or other meetings of healthcare professionals, or international, national or regional congresses, conferences or meetings organized

98

by a professional society or organization (any such occasion, a "Scientific Meeting"), to the extent permitted by applicable Laws, such Party shall provide to the other, prior to submission or presentation, as the case may be, copies of (a) all abstracts that will be submitted for publication, and (b) all posters that will be presented at such Scientific Meeting, in each case, concerning the Product which have been prepared by or on behalf of one of the Parties, for submission or presentation. Commencing with the receipt of any such abstract or poster the receiving Party shall have [\*\*\*] Business Days to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such [\*\*\*] Business Day period, no submission or presentation thereof shall take place) and the Parties shall discuss these observations and suggestions. The receiving Party shall have the right to require modifications to such abstract or poster for patent reasons, trade secret reasons or business reasons, and the sending Party shall remove all Confidential Information of the receiving Party if so requested by the receiving Party. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. The other Party may in good faith require that the publication of the abstract or presentation be suspended for a period of time not exceeding [\*\*\*] if a Patent may be filed using the Data or Know-How covered in the proposed abstract or presentation, which period could be extended to an additional [\*\*\*] period with respect to Data or Know-How useful to enrich the patent applications provided that in the event such additional delay is requested, (i) such requesting Party must reasonably demonstrate the need for such extension by providing the other Party with a detailed rationale and explanation therefor along with a reasonably detailed work plan as to how such delay and experiments may improvement patentability and (ii) the Parties will discuss in good faith the scope and duration of any such extended delay (not to exceed such [\*\*\*]). A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of all final abstracts and all final posters accepted for publication or to be presented [\*\*\*] Business Days prior to the planned publication or presentation thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines). The Parties shall use good faith and commercially reasonable efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.

9.2.3 <u>Written Materials to be Presented at Scientific Meetings</u>. To the extent permitted by applicable Laws, each Party shall provide to the other, prior to submission or presentation, as the case may be, copies of all written materials (other than abstracts and posters) that will be presented at any Scientific Meetings. Commencing with the receipt of any such written material the receiving Party shall have [\*\*\*] Business Days to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during

99

such [\*\*\*] Business Day period, no submission or presentation thereof shall take place) and the Parties shall discuss these observations and suggestions. The receiving Party shall have the right to require modifications to such written materials for patent reasons, trade secret reasons or business reasons, and the sending Party shall remove all Confidential Information of the receiving Party if so requested by the receiving Party. The Party proposing to publish such written materials or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. The other Party may require that the publication of such written materials or presentation be suspended for a period of time not exceeding [\*\*\*] days if a Patent may be filed using the Data or Know-How covered in the proposed written materials or presentation, which period could be extended to an additional [\*\*\*] period with respect to Data or Know-How useful to enrich the patent applications provided that in the event such additional delay is requested, (a) such requesting Party must reasonably demonstrate the need for such extension by providing the other Party with a detailed rationale and explanation therefor along with a reasonably detailed work plan as to how such delay and experiments may improvement patentability and (b) the Parties will discuss in good faith the scope and duration of any such extended delay (not to exceed such [\*\*\*]). A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of all final abstracts and all final posters or other written materials accepted for publication or to be presented [\*\*\*] Business Days prior to the planned publication or presentation thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines). The Parties shall use good faith and commercially reasonable efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.

**Section 9.3 Registries**. Each Party shall be free to disclose any Clinical Study Data generated by such Party concerning the Product in clinical trial registries, in accordance with applicable Laws; <u>provided</u>, <u>however</u>, except to the extent prohibited or otherwise required by applicable Law (and in any event consistent with applicable Law), that the Party proposing to make such disclosure shall have provided the other Party at least [\*\*\*] Business Days prior to such disclosure (to the extent practicable), a detailed description of the proposed disclosure and shall have, in good faith, considered the comments made by the other Party and to delay, upon written request from the other Party, such disclosure by up to [\*\*\*] (or as long as permitted, if less than [\*\*\*] where need to file a patent application.

100

### Section 9.4 Timeline Extension or Deferral of Disclosures.

9.4.1 Each Party agrees that it will not unreasonably withhold, condition or delay its consent to requests for extensions of the above timelines in this <u>ARTICLE 9</u> in the event that material late breaking Data becomes available.

9.4.2 If either Party believes that any proposed press release or other public statement, or any publication, presentation, or other disclosure would be prejudicial to its opportunity to obtain any Patent, then the affected Party shall notify the publishing Party within the timeframe provided for in this <u>ARTICLE 9</u> as applicable, or if not applicable, as soon as practicable after receipt of the proposed press release or other public statement, publication, presentation, or other disclosure, and the publishing Party shall refrain from making such press release, other public statement, publication, presentation or other disclosure for an additional [\*\*\*] Business Days from the last day of the period otherwise provided for herein to enable the preparation and filing of any necessary patent applications.

**Section 9.5** Failure to Object to Disclosure. If the Party proposing any press release or other public statement, or any publication, presentation, or other disclosure referred to in this <u>ARTICLE 9</u> (excluding for the avoidance of doubt any promotional materials) receives no objection from the other Party within the timeframes set forth in the corresponding Section, then, the Party proposing such press release, other public statement, publication, presentation, or other disclosure shall be free to proceed with the same without further reference to or agreement from the other Party; provided, however, that any such publication, presentation, or other disclosure shall acknowledge the other Party's contribution to any Data included therein and otherwise comply with this Agreement.

# **ARTICLE 10 REPRESENTATIONS, WARRANTIES & COVENANTS**

#### Section 10.1 Representations and Warranties of the Parties.

10.1.1 Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

10.1.1.(a) such Party is duly established, validly existing and in good standing under the Laws of the jurisdiction and has full power and authority to enter into this Agreement and to carry out the provisions hereof;

10.1.1.(b) all requisite corporate action on the part of such Party, its directors and stockholders required by applicable Law for the authorization, execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken;

101

10.1.1.(c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof; and

10.1.1.(d) the execution and delivery of this Agreement by such Party do not, and the performance of this Agreement by such Party will not: (i) conflict with, or result in any violation of or default under, any agreement, instrument or understanding, oral or written, to which it or any Affiliate is a party or by which it or any Affiliate is bound; or (ii) violate any provision of any applicable Law.

### Section 10.2 Representations and Warranties of Pieris.

10.2.1 <u>Generally</u>. Pieris hereby represents and warrants to Servier that, as of the Effective Date:

10.2.1.(a) Pieris has the right to grant the rights granted to Servier under this Agreement, and no rights granted to Servier pursuant to this Agreement are in violation of any existing agreement between Pieris or any of its Affiliates and any Third Party;

10.2.1.(b) None of Pieris or its Affiliates, any Third Party acting by or on behalf of Pieris or any of its Affiliates in connection with the research, Development or Manufacture of the Product prior to the Effective Date has been debarred or is subject to debarrent;

10.2.1.(c) Pieris is the owner of or Controls the Pieris Patent Rights listed in <u>Schedule 10.2.1.(c)</u> (with an indication as to which Patent Rights are owned and which are controlled) ("*Existing Pieris Patent Rights*"). Each of the Existing Pieris Patent Rights has been filed in good faith, has been prosecuted in accordance with any applicable duty of candor and has been maintained in a manner consistent with standard industry practice, in each case in each applicable jurisdiction in which such Pieris Patent Rights have been filed, and no official final deadlines with respect to prosecution thereof have been missed and all applicable fees due prior to the Effective Date have been paid on or before the due date for payment;

10.2.1.(d) All inventors of all the Existing Pieris Patent Rights that are owned by Pieris, have been identified as such in the filings with the relevant patent offices and to Pieris' knowledge, all inventors of all the Existing Pieris Patent Rights that are in-licensed by Pieris have been identified as such in the filings with the relevant patent offices;

102

10.2.1.(e) Pieris does not Control other Patent Rights Covering the Products than those listed in <u>Schedule</u> <u>10.2.1.(c)</u>;

10.2.1.(f) where applicable, all of Pieris' and its Affiliates' officers, employees, independent contractors, consultants, and agents as of the Effective Date (other than academics or public or academic institutions subject to <u>Section 2.3.6</u>) performing activities under this Agreement where there is the potential for inventive activity have executed agreements requiring assignment or licensing to Pieris of all inventions Covering a Product made during the course of and as a result of their association with Pieris or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of Pieris or its Affiliate, as applicable;

10.2.1.(g) where applicable, all of Pieris' and its Affiliates' officers, employees, independent contractors, consultants, and agents engaged after the Effective Date (other than academics or public or academic institutions subject to <u>Section 2.3.6</u>) performing activities under this Agreement where there is the potential for inventive activity that have not executed agreements with Pieris prior to the Effective Date will execute agreements requiring assignment to Pieris of all inventions Covering a Product made during the course of and as a result of their association with Pieris or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of Pieris or its Affiliate, as applicable unless otherwise agreed to by the Parties in writing;

10.2.1.(h) There are no agreements (other than the Pieris Background Agreements) to which Pieris or any of its Affiliates is a party under which Pieris or any of its Affiliates obtains or has obtained a license or other right to the Pieris IP from a Third Party to make, use, sell, offer for sale or import the Products in the Field;

10.2.1.(i) To Pieris' knowledge, the Existing Pieris Patent Rights are, or, upon issuance, will be, valid and enforceable patents. There is no pending or, to Pieris' knowledge, threatened claim, suit, action, litigation or other proceeding brought by a Third Party against Pieris or any of its Affiliates (a) challenging the validity or enforceability of any of the Existing Pieris Patent Rights, (b) claiming that the making, using, selling, offering for sale or importing of any of the Products constitutes infringement of such Third Party's Intellectual Property Right(s), or (c) subjecting any of Existing Pieris Patent Rights to interference, reexamination, reissue, revocation, opposition, appeal or other administrative proceedings;

103

10.2.1.(j) Neither Pieris nor any of its Affiliates has received any communications alleging that it has infringed, misappropriated or otherwise violated, or that it would infringe, misappropriate or otherwise violate, through the manufacture, use, import, export, sale, or offer for sale of any of the Products or any portion thereof, any Intellectual Property Rights or Know-How Controlled by any Third Party;

10.2.1.(k) To Pieris' knowledge, there is no Third Party intellectual property that would prevent Pieris from generally practicing the Pieris Platform Technology to Manufacture, Develop and Commercialize Anticalin therapeutics generally, which for clarity and without limitation does not include any specific target or particular Anticalin;

10.2.1.(l) Pieris has taken reasonable precautions to preserve the confidentiality of the Pieris Know-How required to be transferred to Servier under this Agreement;

10.2.1.(m) Pieris has disclosed or made available to Servier in writing, complete and correct copies of (a) any material data from studies of the Lead Product and the Pieris Building Blocks in its possession and (b) all material Regulatory Materials (if any) and correspondence between Pieris and its Affiliates, on the one hand, and any Competent Authority, on the other hand (if any), relating to the Lead Product and the Pieris Building Blocks;

10.2.1.(n) All studies conducted specifically for the Lead Product and the Pieris Building Blocks have been conducted by Pieris or any of its (sub)contractors in accordance with applicable Laws by persons with appropriate education, knowledge and experience;

10.2.1.(o) The documents containing Data and Pieris Know-How disclosed or made available to Servier in the context of the negotiation of this Agreement are true and accurate copies of what they purport to be;

10.2.1.(p) No information or materials provided by Pieris to Servier (whether prepared by Pieris or any subcontractor) contain any materially untrue or, willfully misleading statement of a material fact or willfully omit to state a material fact, with respect to the efficacy, side effects or preclinical or clinical testing of the Lead Product and the Pieris Building Blocks;

104

#### 10.2.1.(q) In relation to the Pieris Background Agreements:

(i) None of the Existing Pieris Patent Rights is licensed from a Third Party, except pursuant to the Pieris Background Agreements. Except under the Pieris Background Agreements, Pieris is not subject to any contractual payment obligations to Third Parties as a result of the execution of this Agreement or the Development, Manufacture or Commercialization of the Products in the Field in the Servier Territory. Pieris has provided a complete, accurate copy of all material terms and conditions of the Pieris Background Agreements to Servier. Pieris will provide an accurate copy of the material terms and conditions of this Agreement to the licensors under the Pieris Background Agreements, redacted for the Parties' sensitive or confidential information.

(ii) The Pieris Background Agreements are a valid and binding obligation and are in full force and effect. All Patents licensed to Pieris under the Pieris Background Agreements, to the extent otherwise being encompassed within the licenses granted to Servier under this Agreement, are Controlled by Pieris for purposes of the licenses granted to Servier under this Agreement;

(iii) Pieris is not in material breach or default (and the delivery and execution of this Agreement will not constitute a breach or default) of the Pieris Background Agreements, and Pieris has not received any written notice from the applicable Third Party licensor under such Pieris Background Agreements (A) that Pieris has materially breached or defaulted thereunder that has not been cured or (B) of any intention of such Third Party licensor to terminate the Pieris Background Agreements; and

(iv) Pieris shall maintain the Pieris Background Agreements, to the extent the rights and licenses granted to Pieris thereunder are sublicensed to Servier hereunder, and shall not modify, amend, terminate or breach the Pieris Background Agreements, if such modification, amendment, termination or breach would adversely affect Servier's rights under this Agreement (after taking into account any period(s) to cure alleged breaches). Pieris shall take reasonable steps to remediate any issue or breach of such Pieris Background Agreements. In the event that Pieris has failed to take prompt efforts to remediate any breach of the Pieris Background Agreements, Servier shall have the right, at Pieris' cost, to step in and remediate such breach.

105

#### Section 10.3 Representations and Warranties of Servier.

10.3.1 <u>Generally</u>. Servier hereby represents and warrants to Pieris that, as of the Effective Date:

10.3.1.(a) Servier has the right to grant the rights granted to Pieris under this Agreement, and no rights granted to Pieris pursuant to this Agreement are in violation of any existing agreement between Servier or any of its Affiliates and any Third Party;

10.3.1.(b) Servier is the owner of or Controls the Servier Patent Rights listed in <u>Schedule 10.3.1.(b)</u> (with an indication as to which Patent Rights are owned and which are controlled) ("*Existing Servier Patent Rights*"). Each of the Existing Servier Patent Rights has been filed in good faith, has been prosecuted in accordance with any applicable duty of candor and has been maintained in a manner consistent with standard industry practice, in each case in each applicable jurisdiction in which such Servier Patent Rights have been filed, and no official final deadlines with respect to prosecution thereof have been missed and all applicable fees due prior to the Effective Date have been paid on or before the due date for payment;

10.3.1.(c) All inventors of all the Existing Servier Patent Rights that owned by Servier, have been identified as such in the filings with the relevant patent offices and to Servier's knowledge, all inventors of all the Existing Servier Patent Rights that in-licensed by Servier have been identified as such in the filings with the relevant patent offices;

10.3.1.(d) Servier does not Control other Patent Rights Covering the Products than those listed in <u>Schedule</u> 10.3.1.(b);

10.3.1.(e) where applicable, all of Servier' and its Affiliates' officers, employees, independent contractors, consultants, and agents as of the Effective Date (other than academics or public or academic institutions subject to <u>Section 2.3.6</u>) performing activities under this Agreement where there is the potential for inventive activity have executed agreements requiring assignment or licensing to Servier of all inventions Covering a Product made during the course of and as a result of their association with Servier or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of Servier or its Affiliate, as applicable;

10.3.1.(f) where applicable, all of Servier' and its Affiliates' officers, employees, independent contractors, consultants, and agents engaged after the Effective Date (other than academics or

106

public or academic institutions subject to <u>Section 2.3.6</u>) performing activities under this Agreement where there is the potential for inventive activity that have not executed agreements with Servier prior to the Effective Date will execute agreements requiring assignment to Servier of all inventions Covering a Product made during the course of and as a result of their association with Servier or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of Servier or its Affiliate, as applicable unless otherwise agreed to by the Parties in writing;

10.3.1.(g) To Servier's knowledge the Servier Patent Rights are, or upon issuance, will be, valid and enforceable patents. There is no pending or, to Servier's knowledge, threatened claim, suit, action, litigation or other proceeding brought by a Third Party against Servier or any of its Affiliates (a) challenging the validity or enforceability of any of Servier Patent Rights or (b) seeking to subject any of Servier Patent Rights to interference, reexamination, reissue, revocation, opposition, appeal or other administrative proceedings.

10.3.1.(h) Servier has taken reasonable precautions to preserve the confidentiality of the Servier Know-How required to be transferred to Pieris under this Agreement;

10.3.1.(i) Servier has disclosed or made available to Pieris in writing, complete and correct copies of any material data from studies of the Servier Building Blocks in its possession;

10.3.1.(j) All studies conducted specifically for the Servier Building Blocks have been conducted by Servier or any of its subcontractors in accordance with applicable Laws by persons with appropriate education, knowledge and experience;

10.3.1.(k) The documents containing Data and Servier Know-How disclosed or made available to Pieris in the context of the negotiation of this Agreement are true and accurate copies of what they purport to be; and

10.3.1.(l) No information or materials provided by Servier to Pieris (whether prepared by Servier or any subcontractor) contain any materially untrue or, willfully misleading statement of a material fact or willfully omit to state a material fact, with respect to the efficacy, side effects or preclinical or clinical testing of any Servier Building Block; and

107

#### 10.3.1.(m) In relation to the Servier Background Contract:

(i) None of the Servier IP is licensed from a Third Party, except pursuant to the Servier Background Contract. Except under the Servier Background Contract, Servier is not subject to any contractual payment obligations to Third Parties as a result of the execution of this Agreement or the Development, Manufacture or Commercialization of the Products in the Field in the Pieris Territory. Servier has provided a complete and accurate copy of all material terms and conditions of the Servier Background Contract to Pieris. Servier will provide an accurate copy of the material terms and conditions of this Agreement to the licensors under the Servier Background Contract, redacted for the Parties' sensitive or confidential information.

(ii) The Servier Background Contract are valid and binding obligations and are in full force and effect. All Patents licensed to Servier under the Servier Background Contract, to the extent otherwise being encompassed within the licenses granted to Pieris under this Agreement, are Controlled by Servier for purposes of the licenses granted to Pieris under this Agreement;

(iii) Servier is not in material breach or default (and the delivery and execution of this Agreement will not constitute a breach or default) of the Servier Background Contract, and Servier has not received any written notice from the applicable Third Party licensor under such Servier Background Contract (A) that Servier has materially breached or defaulted thereunder or (B) of any intention of such Third Party licensor to terminate the Servier Background Contract; and

(iv) Servier shall maintain the Servier Background Contract, to the extent the rights and licenses granted to Servier thereunder are sublicensed to Pieris hereunder, and shall not modify, amend, terminate or breach the Servier Background Contract, if such modification, amendment, termination or breach would adversely affect Pieris' rights under this Agreement (after taking into account any period(s) to cure alleged breaches). Servier shall take reasonable steps to remediate any issue or breach of such Servier Background Contract. In the event that Servier has failed to take prompt efforts to remediate any breach of a Servier Background Contract, Pieris shall have the right, at Servier's cost, to step in and remediate such breach.

10.3.2 **Disclaimer.** EXCEPT AS EXPRESSLY SET FORTH IN <u>Section 10.1</u>, <u>Section 10.2</u> AND <u>Section 10.3</u> ABOVE, NEITHER PARTY MAKES (AND EACH PARTY EXPRESSLY DISCLAIMS) ANY AND ALLY REPRESENTATIONS OR WARRANTIES OF ANY KIND, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED STATUTORY OR OTHERWISE, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OR ANY WARRANTIES THAT MAY ARISE FROM A COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OR TRADE, INCLUDING WITH RESPECT TO ANY INTELLECTUAL PROPERTY RIGHTS, TECHNOLOGY OR CONFIDENTIAL INFORMATION OF A PARTY.

108

#### Section 10.4 Mutual Covenants. Each Party hereby covenants throughout the Term as set forth below.

10.4.1 <u>Compliance</u>. Each Party will, and will cause its Affiliates and Sublicensees to, conduct the Research Collaboration and the Development, Manufacture and Commercialization of the Products in material compliance with all applicable Laws, including current governmental regulations concerning current good laboratory practices (GLP), good clinical practices (GCP) and good manufacturing practices (GMP).

10.4.2 <u>Non-Debarment</u>. Such Party will not, and will cause its Affiliates and Sublicensees not to, employ or use any contractor or agent that employs any individual or entity (a) that has been debarred by a Competent Authority under applicable Laws or convicted of a crime for which such Person could be so debarred, or (b) that is the subject of a debarment investigation or proceeding of a Competent Authority under applicable Laws, in each case of clauses (a) and (b), in the conduct of such Party's, its Affiliates' and Sublicensees' activities under this Agreement.

10.4.3 <u>No Conflict</u>. Such Party shall not, and shall cause its Affiliates and Sublicensees not to, enter into any agreement or other arrangement with a Third Party that conflicts with the rights granted to the other Party under this Agreement.

10.4.4 <u>Licensure</u>. If either Party determines in good faith that the licenses under this Agreement are required to be filed with the Federal Trade Commission ("*FTC*") under the US's Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a) ("*HSR*") or with equivalent foreign Government Authorities under any similar foreign Law, then each Party will promptly prepare and submit any necessary filings and will use commercially reasonable efforts to obtain such approvals and the Effective Date shall occur upon all such HSR or other governmental clearances have been obtained. Each Party will be responsible for its own costs; provided that Servier will pay all filing fee(s) required in the event of an HSR filing or filing for other governmental clearance. Both Parties will use all commercially reasonable efforts to cause the clearance to be obtained as quickly as possible. However, neither Party will be required to adversely affect its legal position (e.g., agree to divestitures or product restrictions) in the interest of expediting such clearance.

#### Section 10.5 Party Covenants.

10.5.1 Pieris shall submit by [\*\*\*] to relevant patent offices the priority patent applications for the [\*\*\*] Building Block and the Lead Product, a draft of which has been communicated to Servier prior to the date hereof, including Servier's reasonable comments on such patent applications.

109

10.5.2 Upon a Party's reasonable request, the other Party shall use Commercially Reasonably Efforts to negotiate and execute appropriate documents (whether through amendment to an existing agreement or a separate side letter) to permit continuation of any sublicense granted under a Pieris Background Agreement or Servier Background Contract in the event of termination of such Pieris Background Agreement or Servier Background Contract, as applicable (due to insolvency or otherwise).

# **ARTICLE 11 INDEMNIFICATION; INSURANCE**

Section 11.1 Pieris Indemnity. Pieris shall defend, indemnify and hold harmless Servier and its Affiliates and their respective directors, officers, agents, representatives, successors, permitted assignees and employees (collectively, the "Servier Indemnitees") from and against any and all liabilities, losses, costs, damages and expenses, including reasonable attorneys' fees (collectively, "Damages"), incurred as a result of or arising out of any claim, suit, action, demand or other proceeding made or brought by a Third Party (each, a "Third Party Claim") against one or more Servier Indemnitees to the extent resulting from (a) the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions of Pieris or its Affiliates or their respective agents, representatives, consultants or independent contractors, in the performance by or on behalf of Pieris of Pieris' obligations under this Agreement, (b) any breach (or allegation of a breach) by Pieris of any representation, warranty or covenant made by Pieris set forth in ARTICLE 10 of this Agreement or any breach or violation of any covenant or agreement of Pieris in or in performance of this Agreement, or (c) solely as it pertains to a Third Party Claim for product liability in the Pieris Territory, the Development, Manufacturing, Commercialization, handling, storage, labeling or transfer of any Product to the extent such Damages were incurred with respect to the Development, Manufacture or Commercialization by or for Pieris or any of its Affiliates or Sublicensees of the Lead Product or a CoDev Collaboration Product in or for the Pieris Territory (including any such activities performed by Servier pursuant to this Agreement); except, in any such case, to the extent such Damages arise out of or result from the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions or breach of this Agreement by Servier or a Servier Indemnitee or matters for which Servier is obligated to indemnify Pieris under Section 11.2.

Section 11.2 Servier Indemnity. Servier shall defend, indemnify and hold harmless Pieris and its Affiliates and their respective directors, officers, agents, representatives, permitted successors, permitted assignees and employees (collectively, the "*Pieris Indemnitees*") from and against any and all Damages incurred as a result of or arising out of any Third Party Claim made or brought against one or more Pieris Indemnitees to the extent resulting from (a) the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions of Servier or its Affiliates or their respective agents, representatives, consultants or independent contractors, in the performance by or on behalf of Servier of Servier's obligations under this Agreement, (b) any breach (or allegation of a breach) by Servier of any representation, warranty or covenant made by Servier set forth in <u>ARTICLE 10</u> of this Agreement or any breach or violation of any covenant or agreement of Servier in or in performance of this Agreement, or (c) solely as

110

it pertains to a Third Party Claim for product liability in the Servier Territory, the Development, Manufacturing, Commercialization, handling, storage, labeling or transfer of any Product to the extent such Damages were incurred with respect to the Development, Manufacture or Commercialization by or for Servier or any of its Affiliates or Sublicensees of the Lead Product or a CoDev Collaboration Product in or for the Servier Territory or for a Servier WW Collaboration Product anywhere in the world (including any such activities performed by Pieris pursuant to this Agreement); except, in any such case, to the extent such Damages arise out of or result from the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions or breach of this Agreement by Pieris or a Pieris Indemnitee or matters for which Pieris is obligated to indemnify Servier under <u>Section 11.1</u>.

#### Section 11.3 Indemnification and Defense Procedures.

11.3.1 Notice of Claim. All claims for indemnification or defense by a Party as provided herein shall be made solely by the Party seeking indemnification or defense of a Third Party Claim or remedies for any Damages (the "*Indemnified Party*"). The Indemnified Party shall give written notice of the same to the other Party (the "*Indemnifying Party*") reasonably promptly after the assertion against the Indemnified Party of any Third Party Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder (a "*Claim Notice*"), provided, however, that failure or delay to provide such Claim Notice shall not affect the Indemnifying Party's indemnification or defense obligations, except to the extent such failure materially and adversely affects the ability to defend such claim. Each Claim Notice must contain a description of the Third Party Claim and the nature and amount of any Damages (to the extent that the nature and amount of such Damages is known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all notices, papers, correspondence, communications and official documents (including court papers) previously received or sent and thereafter that the Indemnified Party Claim.

11.3.2 <u>Assumption of Defense</u>. To the extent permitted by applicable Laws, the Indemnifying Party shall assume the defense and handling of such Third Party Claim, at the Indemnifying Party's sole expense in accordance with <u>Section 11.3.3</u>.

11.3.3 <u>Indemnification Procedure.</u> In assuming the defense of any Third Party Claim, the Indemnifying Party: (a) shall act diligently and in good faith with respect to all matters relating to the defense, settlement or disposition of such Third Party Claim as the defense, settlement or disposition relates to the Indemnified Party; (b) may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Third Party Claim any law firm or counsel reasonably selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; (c) keep the Indemnified Party informed of the status of such Third Party Claim; (d) shall have the right to settle the Claim on any terms

111

the Indemnifying Party chooses, subject to prior notification to the Indemnified Party; provided that the Indemnifying Party shall not settle or otherwise resolve any Third Party Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party, without prior written consent of the Indemnified Party, which may not be unreasonably withheld or delayed. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in its defense of any Third Party Claim for which the Indemnifying Party has assumed the defense in accordance with this <u>Section 11.3.3</u>, and shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification.

11.3.4 <u>Indemnified Party Right to Participate</u>. If the Indemnifying Party fails to conduct the defense and handling of any Third Party Claim in good faith or if the Third Party Claim seeks non-monetary relief, (a) the Indemnified Party may at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Third Party Claim and defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party shall regularly inform the Indemnifying Party of the status of such Claim and consult with the Indemnifying Party but shall have no obligation hereunder to obtain any consent from, the Indemnifying Party in connection therewith, except that the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed); and (b) the Indemnified Party elects to defend or handle such Third Party Claim in accordance with this <u>Section 11.3.4</u>. If the Indemnified Party elects to defend or handle such Third Party Claim in accordance with this <u>Section 11.3.4</u>. If the Indemnified Party elects to defend or handle such Third Party Claim in accordance with this <u>Section 11.3.4</u>. If the Indemnified Party is the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Third Party Claim with its own counsel and at its own expense.

**Section 11.4 Insurance.** During the Term and thereafter for a period of five (5) years, each Party shall procure and maintain adequate insurance coverage with internationally-reputable company or a program of self-insurance (which shall be of types and amounts sufficient to cover the liabilities hereunder, contingent or otherwise of such Party and its Affiliates). It is understood that such insurances shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this <u>ARTICLE 11</u>. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in the insurance coverage.

112

Section 11.5 DISCLAIMER OF LIABILITY. IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE OR OTHERWISE. NOTWITHSTANDING THE FOREGOING, THIS DISCLAIMER DOES NOT APPLY TO LIABILITY OR DAMAGES (A) RESULTING FROM A BREACH OF CONFIDENTIALITY OBLIGATIONS OF A PARTY UNDER <u>ARTICLE 8</u> OR (B) SUBJECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS PURSUANT TO <u>Section 11.1, Section 11.2 OR Section 11.3.</u>

#### **ARTICLE 12 TERM AND TERMINATION**

**Section 12.1 Term.** The term of this Agreement (the "*Term*") will commence on the Effective Date and will extend, unless this Agreement is terminated earlier in accordance with <u>Section 12.2</u>, on a Product-by-Product and country-by-country basis, until such time as the Royalty Term with respect to such Product in such country expires. Upon the natural expiration (as opposed to termination) of the Royalty Term with respect to a Product and country: (a) the licenses granted by Pieris to Servier under this Agreement with respect to such Product shall remain in effect as granted in accordance with this Agreement, shall become irrevocable, fully paid-up and royalty-free licenses and shall last as long as Servier intends to Develop or Commercialize the applicable Product in such country, (b) with regard to the Lead Product and any CoDev Collaboration Product, the licenses granted by Servier to Pieris under this Agreement with respect to such Product shall remain in effect as granted in accordance with this Agreement, shall become irrevocable, fully paid-up and royalty-free licenses and shall last as long as Pieris intends to Develop or Commercialize the applicable Product in such country, (b) with respect to such Product shall remain in effect as granted in accordance with this Agreement, shall become irrevocable, fully paid-up and royalty-free licenses and shall last as long as Pieris intends to Develop or Commercialize the Lead Product or applicable CoDev Collaboration Product in such country and (c) <u>Section 6.2</u> shall no longer apply to the Parties solely with respect to the Development and Commercialization of such Product in such country (including the Manufacture thereof solely for such Development and Commercialization purposes).

**Section 12.2** Termination. Notwithstanding anything in this Agreement or elsewhere to the contrary, subject to <u>Section 12.3.7</u> below, this Agreement may be terminated as follows:

12.2.1 <u>Termination for Material Breach</u>. Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or materially defaulted in the performance of any of its obligations hereunder which breach or default is material in the overall context of the Agreement, and such breach has continued for ninety (90) days after written notice thereof was provided to the breaching Party by the non-breaching Party which clearly describes the remedies that the non-breaching Party intends to apply should the breach remain uncured. Any such termination shall become effective at the end

113

of such ninety (90) day period if, prior to the expiration of the ninety (90) day period, the breaching Party has not cured any such breach or default, provided, that with respect to a breach of such Party's Commercially Reasonable Efforts obligations to Develop or Commercialize the Product, such cure period shall be extended for a period not to exceed an additional ninety (90) days in the event such breaching Party has, within the original ninety (90) day period prepared and communicated to the non-breaching Party, a remediation plan reasonably designed to cure such breach or default within a reasonable period of time (which plan is reasonably acceptable to the non-breaching Party) and such breaching Party continues to diligently use Commercially Reasonable Efforts to implement such plan throughout such period. If the allegedly breaching Party disputes the breach and provides written notice of that dispute to the other Party, the matter shall be addressed under the dispute resolution provisions in <u>Section 13.3</u>, and the notifying Party may not terminate this Agreement until it has been finally determined under <u>Section 13.3</u> that the Agreement was materially breached as described above. The non-breaching Party will have the right to terminate this Agreement with respect to either the entire Product or only the countries to which the uncured material breach relates, provided that this Agreement cannot be terminated only with respect to some (but not all) countries of the European Union.

12.2.2 <u>Termination by Mutual Agreement</u>. This Agreement (as a whole or on a Product-by-Product and country-by-country basis) may be terminated by the mutual written consent of the Parties.

12.2.3 <u>Termination by Servier for Convenience</u>. Beginning twelve (12) months after the Effective Date, Servier may terminate this Agreement on a Product-by-Product basis and/or on a country-by-country basis by providing one hundred eighty (180) days' prior written notice to Pieris, with such termination being effective upon the end of such 180-day notice period.

12.2.4 <u>Termination for Insolvency</u>. Either Party may terminate this Agreement if, at any time, the other Party will file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, or if the other Party proposes a written agreement of composition or extension of substantially all of its debts, or if the other Party will be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within ninety (90) days after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party will make an assignment of substantially all of its assets for the benefit of creditors. Upon the bankruptcy of any Party, the non-bankrupt Party will further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, will be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

114

#### 12.2.5 <u>Termination for Safety</u>.

12.2.5.(a) Servier may terminate this Agreement with respect to (a) the Lead Product or (b) any Collaboration Product, CoDev Collaboration Product or Servier WW Collaboration Product, immediately upon written notice to Pieris, that such Product reasonably demonstrates a safety issue in humans.

12.2.5.(b) Pieris may terminate this Agreement with respect to the Lead Product or any CoDev Collaboration Product, immediately upon written notice to Servier, that such Product demonstrates a safety issue in humans.

12.2.5.(c) For purposes of this <u>Section 12.2.5</u>, "safety issue" means instances in which the FDA and the EMA require that the Development, Manufacture or Commercialization be stopped.

#### Section 12.3 Effects of Termination.

12.3.1 <u>Effects of Termination</u>. In the event of any termination of this Agreement in its entirety or with respect to any given Product (a) by Servier for convenience pursuant to <u>Section 12.2.3</u>, (b) by Pieris for Servier's material breach pursuant to <u>Section 12.2.1</u> (without prejudice to any other remedies of Pieris, including the right to claim damages), (c) by Pieris for Servier's insolvency pursuant to <u>Section 12.2.4</u>, or (d) by Servier, where it is dropping a Product pursuant to <u>Section 5.2.1</u>, the following terms shall apply:

12.3.1.(a) At Pieris' request, Servier will return to Pieris or destroy (and certify such destruction to Pieris), at Pieris' option, all Pieris' Confidential Information related to the terminated Product(s) and Pieris Know-How related to the terminated Product(s) (provided that Servier shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by applicable Law or regulatory requirement);

12.3.1.(b) Pieris shall have the right to acquire some or all of the inventory of the terminated Product, as requested by Pieris, in the possession of Servier and its Affiliates as of the date of such termination, provided that, if Pieris so acquires any or all such inventory, Pieris shall reimburse Servier the cost incurred by Servier for such inventory;

12.3.1.(c) All licenses and sublicenses granted by Pieris to Servier hereunder shall terminate, provided however that they will continue solely to enable Servier to (i) complete sales of Products for any purchase orders that were in place prior to the effective date of termination and (ii) sell off any existing inventory of Products that Pieris does not purchase pursuant to <u>Section 12.3.1.(b)</u>; thereafter, Servier will discontinue Commercialization of the applicable Product in the applicable countries.

115

12.3.1.(d) To the extent requested by Pieris, Servier shall enter into an agreement whereby Servier assigns its rights or grants an exclusive license to Pieris, under Servier IP that is used or necessary to further Develop, Manufacture and Commercialize the terminated Products, at the terms and conditions applicable to Dropped Products by Servier pursuant to <u>Section 5.2.1.(c)</u>, including adequate indemnities to be agreed upon; provided that, with respect to each such terminated Product, such Product will be deemed a "Dropped Product", Servier will be deemed the "Dropping Party," and the effective date of termination under this Section will be deemed the "Drop Date" for such Product; and

12.3.1.(e) At the request of Pieris, the Parties will discuss in good faith the wind-down of any ongoing Clinical Studies or Manufacturing campaigns for the terminated Product(s) currently being conducted by or on behalf of Servier or Pieris or their Affiliates at the time of termination; provided that, absent such an agreement, such ongoing Clinical Studies or ongoing Manufacturing campaigns shall be continued (and funded or co-funded) for [\*\*\*] following the notice of termination.

12.3.1.(f) Servier will, as promptly as practicable, and subject to Pieris' reasonable assistance, to the extent legally permissible (including to the extent permitted under Servier's obligations to Third Parties on the effective date of termination), (i) transfer and assign to Pieris or Pieris' designee Servier's right, title and interest in and to all material governmental or regulatory filings and approvals (including all Regulatory Approvals and pricing approvals, and Regulatory Materials, in all cases, specifically and exclusively relating to the Development, Manufacture or Commercialization of the terminated Products, and (ii) transfer to Pieris or Pieris' designee copies of all material Data, Know-How, Clinical Study data and safety data in Servier's possession and Control to the extent specifically related to and required for the research, Development, Manufacture or Commercialization of the terminated Product-related matters involving Regulatory Authorities until all Regulatory Approvals and other regulatory filings hereunder have been assigned to Pieris or its designee. In the event of (x) failure to obtain assignment or (y) with respect to regulatory items that would otherwise fall within (i) and (ii) but for such materials not being specifically related to the terminated Products, but nonetheless which are necessary for the Development, Manufacture or Commercialization of the terminated Products above, in each of (x) and (y) Servier hereby consents and grants to Pieris the right to access and reference (without any further action required on the part of Servier, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to all terminated Products.

12.3.1.(g) If Servier or its Affiliates are manufacturing finished product with respect to terminated Products on the effective date of termination, at

116

Pieris' option (which must be exercised in writing to Servier within [\*\*\*] of the effective date of termination), Servier or its Affiliates will use Commercially Reasonable Efforts to supply such finished product (but solely in the form as such terminated Product was being manufactured by Servier as of the effective date of termination) to Pieris at [\*\*\*] until the earlier of (i) such time as Pieris has procured or developed its own source of such finished product supply, or (ii) [\*\*\*] following the effective date of termination. The Parties will promptly negotiate a supply and related quality agreement to govern the specific terms and conditions of such supply.

12.3.1.(h) If Pieris so requests within [\*\*\*] of the effective date of termination, Servier will use Commercially Reasonable Efforts, to the extent legally permissible (including to the extent permitted under Servier's obligations to Third Parties on the effective date of termination), to assign to Pieris any Third Party agreements that are specific to and exclusively relating to the Development, Manufacture or Commercialization of the terminated products to which Servier is a party, subject to any required consents of such Third Party.

12.3.1.(i) Servier will use Commercially Reasonable Efforts, and subject to Pieris' reasonable assistance, to the extent legally permissible (including to the extent permitted under Servier's obligations to Third Parties on the effective date of termination), to promptly transfer and assign or exclusively license (or, if applicable, will cause its Affiliates to assign) to Pieris all of Servier's (and such Affiliates') worldwide right, title and interest in and to any registered trademarks or registered internet domain names that are specific to and exclusively used for the terminated Products (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of Servier or any of its Affiliates or any other products of Servier or any of its Affiliates).

12.3.1.(j) More generally, Servier shall use Commercially Reasonable Efforts to ensure a smooth and orderly transition of the Product, including any Development, Manufacturing, or Commercialization activities ongoing at the time of termination to Pieris, pursuant to a termination agreement to be negotiated by the Parties within [\*\*\*] following the termination notice. Such agreement shall be consistent with this <u>Section 12.3</u>.

12.3.1.(k) For avoidance of doubt, the non-compete set forth in <u>Section 6.2</u> regarding the terminated Product (including the discontinued targets pairs therein, except to the extent such target pairs are contained within a Product for which this Agreement remains in effect) will no longer apply.

12.3.1.(1) Notwithstanding this Section <u>12.3.1</u>, if this Agreement is Terminated by Pieris for Servier's material breach pursuant to <u>Section 12.2.1</u> (including breach of any exclusive license to Pieris or breach of any non-compete), then the licenses granted to Pieris shall continue and Pieris shall owe Servier [\*\*\*] of the royalties set forth in <u>Section 5.2.1.(c)(i)</u>.

117

12.3.2 <u>Other Cases of Termination</u>. In the event of a termination of this Agreement with respect to one or more Products pursuant to <u>Sections 12.2.2</u> (Mutual Agreement) or <u>Section 12.2.5</u> (Safety), by Servier pursuant to <u>Section 12.2.1</u> (Material Breach by Pieris) or by Servier pursuant to <u>Section 12.2.4</u> (Pieris Insolvency), without prejudice to any other remedies of Servier, including the right to claim damages, the following terms shall apply:

12.3.2.(a) All Development, Manufacture and Commercialization of such terminated Product by either Party shall immediately cease;

12.3.2.(b) The licenses granted by each Party to the other under, respectively, the Building Block IP and Product Specific IP and the Pieris IP and Servier IP shall immediately terminate;

12.3.2.(c) The non-compete set forth in <u>Section 6.2</u> regarding the terminated Product (including the discontinued targets pairs therein, except to the extent such target pairs are contained within a Product for which this Agreement remains in effect) will no longer apply; and

12.3.2.(d) Each Party shall retain the right to use any Data generated with respect to the terminated Product for such Party's internal, research purposes.

#### 12.3.3 Termination for Safety Concern.

12.3.3.(a) If Servier wishes to terminate this Agreement with respect to a Product for a safety concern that does not rise to the level of a safety issue as set forth in <u>Section 12.2.5</u>, then Servier shall be permitted to do so under the terms and conditions of a termination for convenience by Servier under <u>Sections 12.2.3</u> and with the effects described under <u>Section 12.3.1</u> except that (i) Servier's obligation to provide continued supply of the Product for [\*\*\*] under <u>Section 12.3.1(g)</u> and (ii) Servier's obligation to continue and fund or co-fund ongoing Clinical Studies and ongoing Manufacturing campaigns for [\*\*\*] under <u>Section 12.3.1.(e)</u> shall not apply. Instead, the Parties shall discuss and agree in good faith on an appropriate amount of time for continued supply, continuation of ongoing Clinical Studies and ongoing Manufacturing campaigns and funding of continued development in order to permit an orderly transition of the Product to Pieris so that it may continue Development of such Product, depending on the circumstances and nature of the safety concern. Such agreement shall also include appropriate indemnification provisions for Servier.

118

12.3.3.(b) If Pieris wishes to terminate this Agreement with respect to the Lead or a CoDev Product for a safety concern that does not rise to the level of a safety issue as set forth in <u>Section 12.2.5</u>, then Pieris shall be permitted to do so under the terms and conditions with the effects described under <u>Sections 12.3.1(b)</u>, (c), and (e)–(j) applied to Pieris *mutatis mutandis* except that (i) Pieris's obligation to provide continued supply of the Product for [\*\*\*] under <u>Section 12.3.1.(g)</u> and (ii) Pieris's obligation to continue and fund or co-fund ongoing Clinical Studies and ongoing Manufacturing campaigns for [\*\*\*] under <u>Section 12.3.1.(e)</u> shall not apply. Instead, the Parties shall discuss and agree in good faith on an appropriate amount of time for continued supply, continuation of ongoing Clinical Studies and ongoing Manufacturing campaigns and funding of continued development in order to permit an orderly transition of the Product to Servier so that it may continue Development of such Product, depending on the circumstances and nature of the safety concern. Such agreement shall also include appropriate indemnification provisions for Pieris.

12.3.3.(c) For purposes of this <u>Section 12.3.3</u>, "safety concern" means the applicable Party's reasonable and good faith belief, that there is an unacceptable risk for harm in humans based upon: (i) pre-clinical safety data, including data from animal toxicology studies; or (ii) the observation of a serious adverse effect in humans after a Product has been administered to or taken by humans, such as during a Clinical Study or after the launch of such Product.

12.3.4 <u>Alternative to Termination for Material Breach</u>. In the event of a material breach or default by Pieris that would otherwise be of a sufficiently material nature to allow Servier to terminate the Agreement pursuant to <u>Section 12.2.1</u>, Servier may, in lieu of terminating the Agreement, and in addition to any other remedies Servier may have with respect to such material breach, elect the following:

12.3.4.(a) (i) the licenses granted to Servier hereunder shall continue and (ii) the provisions of this Agreement shall terminate with the exception of: (1) the milestone, royalty and payment terms under <u>Section 2.6</u>, <u>Section 3.6</u>, and <u>ARTICLE 4</u> (as applicable and as adjusted pursuant to this <u>Section 12.3.4</u>), (2) all terms required to enforce such payment terms, such as the financial reporting, audit and record keeping provisions, and (3) all other terms that would otherwise survive termination.

119

12.3.4.(b) In addition, Servier may request the arbitral tribunal to reduce all future milestone and Royalty payments to be paid to Pieris under this Agreement by a percentage comprised between [\*\*\*] as determined by the arbitral tribunal in its sole discretion, depending on the degree of materiality of the material breach referred to it or the value of the Product. The determination of the arbitral tribunal shall be final and binding.

12.3.4.(c) After submission of any Dispute regarding such material breach to arbitration pursuant to <u>Section 13.3</u>, Servier may elect to reduce all milestone and Royalty payments due to Pieris under this Agreement by [\*\*\*] (i.e., to only pay to Pieris [\*\*\*] of such amounts when they become) and place the remaining [\*\*\*] in escrow with a Third Party escrow agent reasonably acceptable to the Parties and which has entered into a three party agreement with Pieris and Servier, until the matter is resolved by the arbitral tribunal. If the arbitral tribunal awards Servier: (i) damages in excess of the amount placed in escrow, the escrow agent shall return to Servier the amounts placed in escrow and Pieris shall pay the difference to Servier or (ii) damages lower than the amount placed in escrow, the escrow agent shall pay to Servier the amount of damages awarded by the arbitral tribunal and pay the balance of the amount in escrow to Pieris. After the arbitration award has been rendered, Servier shall pay to Pieris the milestone and Royalty payments when they become due as reduced by the arbitral tribunal in accordance with <u>Section 12.3.4.(b)</u>.

12.3.4.(d) Notwithstanding anything to the contrary in the Agreement, the breach of Pieris' exclusivity under <u>Section 2.1</u> or <u>Section 3.2</u> or non-compete covenant under <u>Section 6.2.1</u> shall be deemed a material breach of Pieris of sufficiently material nature to allow Servier to terminate the Agreement pursuant to <u>Section 12.2.1</u> (subject to the opportunity to cure and dispute resolution as provided in that Section and the provision of Section 12.3.4(c) pending such dispute resolution). In such case, the provisions of <u>Section 12.3.4.(a)</u> shall apply and the Parties agree that the milestone and Royalty payments due to Pieris shall be [\*\*\*].

<u>12.3.5</u> <u>Rights in Bankruptcy</u>. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for all purposes of Section 365(n) of the United States Bankruptcy Code and of any similar or analogous provisions of applicable Laws outside of the United States (the "Bankruptcy Code"), licenses and rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. Each Party agrees that the other Party, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. In the event of the commencement of a bankruptcy

120

proceeding by or against a Party under the Bankruptcy Code (the "*Insolvent Party*"), the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property and Know-How licensed to such Party under this Agreement and held by such first Party and its successors and assigns (and all embodiments of such intellectual property and Know-How), provided that, a Party shall not be required to provide any duplicate copies and embodiments of such intellectual property or Know-How to the other Party so long it has already provided such intellectual property and Know-How it is required to provide to under this Agreement, and, if not already in its possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefore, unless the Insolvent Party continues to perform all of its obligations under this Agreement, or (b) if not delivered or granted under (a) above, following the rejection of this Agreement by or on behalf of the Insolvent Party upon written request therefore by the other Party.

12.3.6 <u>Conditional Split</u>. Without prejudice to <u>Section 12.3.5</u> and without limiting the Parties' respective rights hereunder, within [\*\*\*] of the Effective Date, the Parties shall agree on and shall implement a mechanism ensuring Servier's continued license under Pieris IP to the extent this Agreement is terminated or rejected, including splitting this Agreement into two separate agreements: (i) an irrevocable license which a receiver cannot discontinue; and (ii) a collaboration agreement.

12.3.7 Survival. The termination or expiration of this Agreement shall not affect any payment of any debts or obligations accruing prior to or after such date of termination or expiration. The provisions of ARTICLE 1 (to the extent necessary to give effect to the surviving provisions), Section 2.1.5.(e) (the first sentence), Section 2.3.4.(a), Section 2.3.4.(b) (the first and second sentences), Section 2.5.4 (last sentence with respect to Product sold by or on behalf of such Party, its Affiliates or Sublicensees after the Term during any sell-off period permitted under Section 12.3.1.(c)), Section 2.6 (with respect to Net Sales accrued following the Term during a permitted sell-off period under Section 12.3.1.(c)), Section 3.6 (with respect to Net Sales accrued following the Term during a permitted sell-off period under Section 12.3.1.(c)), Sections 4.1 and 4.2 (with respect to the last Calendar Quarter of the Term or following the Term for any permitted sell-off period under Section 12.3.1.(c) and for final post-Term accounting) Section 4.3, Section 4.4 (for the duration specific therein), Section 5.1.3.(b), Sections 5.2.1.(b), 5.2.1.(c)(i) and 5.2.1.(d) (solely as applicable with respect to the particular Dropped Product), Section 7.1, Section 7.2 (solely with respect to Intellectual Property invented under this Agreement that is jointly owned by the Parties pursuant to the terms of this Agreement), Section 7.3 (last three sentences), Section 7.5 (solely with respect to Patents invented under this Agreement that are jointly owned by the Parties pursuant to the terms of this Agreement), Section 7.6.4 ARTICLE 8, ARTICLE 11, Section 12.1 (last sentence solely upon the natural expiration of the Agreement), Sections 12.3.1, 12.3.2, 12.3.3, 12.3.5, and 12.3.7, and ARTICLE 13 will survive the expiration or any termination of this Agreement for any reason, in accordance with their respective terms and conditions, and for the respective duration stated therein, and where no duration is stated, will survive indefinitely. In addition, any Section that is referred to in the above listed Sections shall survive solely for the interpretation or enforcement of the latters.

121

#### **ARTICLE 13 MISCELLANEOUS**

**Section 13.1 Restrictions; No Other Licenses.** Except as expressly set forth hereunder, neither Party grants to the other Party any rights, licenses or covenants in or to any Intellectual Property Rights, whether by implication, estoppel, vicariously, indirectly or otherwise, other than the license rights that are specifically and expressly granted under this Agreement. All rights not specifically and expressly granted by a licensing party under this Agreement are reserved by such licensing party and may be used or practiced by such licensing party for any purpose.

**Section 13.2 Public Announcements.** Except where otherwise expressly permitted hereunder and except as required by applicable Law, neither Party will make any public announcement of any information regarding this Agreement or any activities under this Agreement without the prior written approval of the other Party, which approval will not be unreasonably withheld or delayed. Each Party will submit to the other Party any proposed announcements at least thirty (30) days prior to the intended date of publication of such announcement to permit review and approval. The Parties agree to issue the joint press release attached hereto as <u>Exhibit 13.2</u> on or the day after the Effective Date.

#### Section 13.3 Dispute Resolution.

13.3.1 <u>Arbitration</u>. In the event a dispute arises (each, a "*Dispute*"), the Alliance Managers will attempt in good faith to resolve such Dispute, failing which either Party may cause such Dispute to be referred to the Executive Officers for resolution. The Executive Officers shall attempt in good faith to resolve such Dispute by unanimous consent. If the Executive Officers cannot resolve such Dispute within [\*\*\*] of the matter being referred to them, then either Party may submit such Dispute to arbitration for final resolution by arbitration request (the "*Arbitration Request*") under the Rules of Arbitration of the International Chamber of Commerce (the "*Rules*") by three (3) arbitrators appointed in accordance with the said Rules (each such arbitration, an "*Arbitration*"). Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be Zurich, Switzerland. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses of Article 6(4) of the Rules, the Parties agree that claims arising out of or in connection with this Agreement and the Platform Agreement may be determined together in a single arbitration. For purposes of Article 10 of the Rules, the Parties agree that any

122

Party may request the consolidation of any arbitration subject to this Agreement with any arbitration subject to the Platform Agreement, even if the parties to the respective arbitrations are not identical. Unless the Parties subsequently agree otherwise, the arbitrations shall be consolidated into the arbitration that commenced first.

13.3.2 <u>Confidentiality</u>. Except to the limited extent necessary to comply with applicable Law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrators' award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

13.3.3 <u>Communications with Internal Counsel</u>. In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon the members of its internal legal department to provide advice to such Party and its directors, employees and agents on legal matters. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

**Section 13.4** Governing Law. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the Laws of [\*\*\*], excluding its rules of conflict of laws.

**Section 13.5** Assignment. This Agreement will not be assignable by either Party, nor may either Party delegate its obligations or otherwise transfer any licenses granted herein or other rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Party hereto, which consent will not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, each Party may assign this Agreement, without the consent of the other Party, to an Affiliate or to its Third Party successor in connection with a merger, consolidation, sale of all or substantially all of the assets to which this Agreement pertains or that portion of its business pertaining to the subject matter of this Agreement, or any Change of Control of such Party; provided that the assignee assumes all of the assigning Party's obligations under this Agreement, subject to this <u>Section 13.5</u>. Any assignment in violation of this provision is void and without effect.

123

**Section 13.6** Acquiror IP. Notwithstanding anything to the contrary in this Agreement, in the event of an acquisition of a Party or its business by an Acquiror after the Effective Date, whether by merger, asset purchase or otherwise, as to any such Acquiror, the non-acquired Party shall not obtain rights, licenses, options or access to any Intellectual Property Rights or Know-How, product candidates or products that are held by the Acquiror or any Affiliate of the Acquiror that becomes an Affiliate of the acquired Party as a result of such acquisition (but excluding the acquired Party itself), that were not generated through any use or access to the Intellectual Property Rights or Know-How of the acquired Party, or that are not used by the acquired Party in connection with a Product under this Agreement.

**Section 13.7** Binding Agreement. This Agreement, and the terms and conditions hereof, will be binding upon and will inure to the benefit of the Parties and their respective successors, heirs, administrators and permitted assigns.

**Section 13.8 Force Majeure.** Except for payment obligations under this Agreement, no Party will be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to force majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, "force majeure" is defined as causes beyond the control of the Party, including, without limitation, acts of God; Laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In the event of force majeure, Pieris or Servier, as the case may be, will immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice will thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as such Party is so disabled, up to a maximum of [\*\*\*], after which time the Party not affected by the force majeure may terminate this Agreement. To the extent possible, each Party will use reasonable efforts to minimize the duration of any force majeure.

**Section 13.9** Notices. Any notice or request required or permitted to be given under or in connection with this Agreement will be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), email or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Pieris:

Pieris Pharmaceuticals GmbH Lise-Meitner-Strasse 30 85354 Freising, Germany Attention: [\*\*\*]

124

Confidential

With a copy to: Pieris Pharmaceuticals Inc. 255 State Street, 9th Floor Boston, MA 02109 Attention: [\*\*\*]

If to Servier:

Les Laboratoires Servier 50 rue Carnot 92284 Suresnes Cedex France Attention: [\*\*\*] Facsimile: [\*\*\*] Email: [\*\*\*]

With a copy to: Attention: [\*\*\*] Les Laboratoires Servier 50 rue Carnot 92284 Suresnes Cedex France

or to such other address for such Party as it will have specified by like notice to the other Parties, provided that notices of a change of address will be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery will be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery will be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery will be deemed to be the third (3rd) day after such notice or request was deposited with the postal service. If sent by email, the date of delivery will be deemed to be the day that the Party giving notice receives electronic confirmation of sending from its email provider.

**Section 13.10** Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances will be construed as a continuing waiver of such condition or term or of another condition or term.

**Section 13.11** Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such

125

jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

**Section 13.12** Entire Agreement. This Agreement, including the schedules and exhibits hereto (including the Platform Agreement), sets forth all the covenants, promises, agreements, appendices, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties relating to the subject matter hereof, including the Prior CDA. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. To the extent of any conflict between the terms of this Agreement and its schedules and exhibits, or any related agreement, the terms of this Agreement shall govern.

**Section 13.13** Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party will assume, either directly or indirectly, any liability of or for the other Party. Neither Party will have the authority to bind or obligate the other Party nor will either Party represent that it has such authority.

**Section 13.14** Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

**Section 13.15 Construction of Agreement.** The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement will be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires

126

otherwise: (a) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (b) any reference to any applicable Law herein shall be construed as referring to such applicable Law as from time to time enacted, repealed or amended; (c) any reference herein to any person shall be construed to include the person's permitted successors and assigns; (d) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (e) all references herein to Articles, Sections, or Schedules, unless otherwise specifically provided, shall be construed to refer to Articles, Sections or Schedules of this Agreement; (f) provisions that require that a Party, the Parties or any Committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, electronic mail, letter, approved minutes or otherwise (but excluding instant messaging); (g) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or" and (h) the words "will" and "shall" will have the same meaning in this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.

**Section 13.16** Compliance with applicable Law. Each Party's obligations under this Agreement shall be subject to such Party's compliance with applicable Law applicable to its performance and its other obligations under the Agreement (including any anti-corruption, export control, environmental, hazardous substance, and data privacy and security Laws).

**Section 1.2** No Third Party Beneficiary. Subject to <u>Section 5.1.3.(b)</u>, nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Parties and their respective Affiliates, successors and assigns, any rights or remedies under or by reason of this Agreement.

**Section 13.17 Counterparts.** This Agreement may be signed in counterparts, each and every one of which will be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures will be treated as original signatures.

[Remainder of page intentionally left blank; signature page follows]

127

IN WITNESS WHEREOF, the Parties have caused this License and Collaboration Agreement to be executed by their duly authorized representatives.

## For Pieris Pharmaceuticals, Inc.

By: /s/ Stephen S. Yoder Name: Stephen Yoder Title: President and CEO

## For Les Laboratoires Servier

By:	/s/ Christian Bazantay
Name:	Mr. Christian BAZANTAY
Title:	Proxy
2	/s/ Eric Falcand
2	/s/ Eric Falcand Mr. Eric FALCAND

#### For Institut de Recherches Internationales Servier

By: /s/ Emmanuel Canet

Name: Dr. Emmanuel Canet

Title: Senior Executive Vice-President Research & Development

Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

#### For Pieris Pharmaceuticals GmbH

# By: /s/ Stephen S. Yoder

Name: Stephen Yoder Title: Managing Director

#### **Exhibit and Schedule Index**

Schedule 1.177: Pieris Designated CoDev Collaboration Products

Schedule 1.182: Pieris Patent Rights

Schedule 1.184: Pieris Platform IP

Schedule 1.234: Servier Patent Rights

Schedule 3.1.1.(b): Initial Collaboration Products

Schedule 10.2.1.(c): Existing Pieris Patent Rights

Schedule 10.3.1.(b): Existing Servier Patent Rights

Exhibit 1.141: Lead Product DCN Criteria - Required Data

**Exhibit 1.193: Platform Agreement** 

Exhibit 2.1.4.(a): Lead Product Know-How Initial Transfer List

Exhibit 2.1.4.(b): Lead Product and Collaboration Products Know-How Ongoing Transfer List

Exhibit 2.3.1.(a): Lead Product Joint Development Plan and Budget

Exhibits 3.1.2.(a)1-7: Collaboration Product - Collaboration Plans and Budgets

Exhibit 3.2.5.(a): Collaboration Product Know-How Initial Transfer List

Exhibit 5.2.1 (c) (ii): Financial Terms for Pieris Drop of the Lead Product

Exhibit 13.2: Joint Press Release

### Pieris Designated CoDev Collaboration Products

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# **Pieris Patent Rights**

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# **Pieris Platform IP**

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### **Servier Patent Rights**

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#### Schedule 3.1.1.(b)

# **Initial Collaboration Products**

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### Schedule 10.2.1.(c)

### **Existing Pieris Patent Rights**

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### Schedule 10.3.1. (b)

# **Existing Servier Patent Rights**

[\*\*\*, 1 page]

### <u>Exhibit 1.141</u>

### Lead Product DCN Criteria – Required Data

[\*\*\*, 1 page]

## Exhibit 1.193

### Form of Platform Agreement

[Filed as Exhibit 10.16 to the Registrant's Form 10-K for the year ended December 31, 2016]

## Exhibit 2.1.4.(a)

# Lead Product Know-How Initial Transfer List

[\*\*\*, 1 page]

## Exhibit 2.1.4.(b)

Lead Product and Collaboration Products Know-How Ongoing Transfer List

# [\*\*\*, 1 page]

### Exhibit 2.3.1.(a)

# Lead Product Joint Development Plan and Budget

# [\*\*\*, 13 pages]

## Exhibits 3.1.2.(a) 1-7

### **Collaboration Product - Collaboration Plans and Budgets**

# [\*\*\*, 1 page]

# Collaboration Plan and Budget [\*\*\*]

[\*\*\*, 12 pages]

# Collaboration Plan and Budget [\*\*\*]

[\*\*\*, 12 pages]

# Collaboration Plan and Budget [\*\*\*]

[\*\*\*, 11 pages]

# Collaboration Plan and Budget [\*\*\*]

[\*\*\*, 10 pages]

## Exhibit 3.2.5.(a)

# **Collaboration Product Know-How Initial Transfer List**

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# Exhibit 5.2.1(c) (ii)

## Financial Terms for Pieris Drop of the Lead Product

Development Milestone	Amount
Start of Phase 1 Clinical Study	[***]
Start of Phase 2a Clinical Study or Phase 1 Expansion Cohorts	[***]
Start of Pivotal Clinical Study	[***]

[\*\*\*]

Development Milestone	Amount
[***] filing [***]	[***]
[***] filing [***]	[***]
[***] filing [***]	[***]
[***] Filing	[***]
Development Milestone	Amount
Marketing Approval [***]	[***]
Marketing Approval [***]	[***]
Marketing Approval [***]	[***]
[***] Marketing Approvals [***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Royalties (for sales outside of the United States)	Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

#### Sales Milestones (for sales outside of the United Sates) Annual Calendar Year - Net Sales Threshold

Annual Calendar Year - Net Sales Threshold	Amount
[***]	[***]
[***]	[***]
[***]	[***]

## For the United States

Development Milestone	Amount
[***] filing [***]	[***]
[***] filing [***]	[***]
[***] filing [***]	[***]
Development Milestone	Amount
Marketing Approval [***]	[***]
Royalties (for sales in the United States)	Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

#### Sales Milestones (for sales in the United Sates) Not Sol A

Annual Calendar Year - Net Sales I nreshold	Amount
[***]	[***]
[***]	[***]
[***]	[***]

For avoidance of doubt, the amounts set forth herein shall be subject to the same payment terms as the development and sales milestone payments and royalties set forth in Section 2.6 or Section 3.6 and the royalty adjustments and other payment terms set forth in ARTICLE 4.

#### Exhibit 13.2

#### Joint Press Release

#### Pieris Pharmaceuticals and Servier Forge Strategic Immuno-oncology Co-development Alliance

- Pieris and Servier, an independent international pharmaceutical company headquartered in France with annual sales of more than EUR4 billion, to jointly pursue several bispecific therapeutic programs including Pieris' proprietary dual checkpoint inhibitor PRS-332
- Alliance includes four additional bispecific programs and may be expanded to a total of eight immuno-oncology programs (including PRS-332); Pieris has option to co-develop and retain US rights for 4 of these programs, including PRS-332
- Pieris to receive EUR30 million (\$31.3 million USD) upfront, up to EUR324 million (\$338 million) in success-based payments for PRS-332, up to EUR193 million (\$201 million) in success-based payments for each of the other programs and up to doubledigit royalties
- Pieris will host an investor conference call on Thursday, January 5, 2017 at 8:30 AM (EST) to discuss the collaboration

**Boston, MA, and Suresnes, France, 5 January 2017 – Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)**, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform, and Servier, an independent international pharmaceutical company, today announced a broad collaboration in immuno-oncology (IO). Despite the impressive clinical efficacy of checkpoint inhibitors to date, a majority of patients fail to respond to approved therapies. The collaboration seeks to address this significant unmet clinical need by advancing a series of novel molecules, including multiple dual immune checkpoint blockade approaches.

Under the collaboration, Pieris and Servier will initially pursue five bispecific therapeutic programs, led by Pieris' PRS-332 program, a potentially best-in-class PD-1-targeting bispecific checkpoint inhibitor. Pieris and Servier will jointly develop PRS-332 and split commercial rights geographically, with Pieris retaining all commercial rights in the United States and Servier having commercial rights in the rest of the world. The four additional committed programs have been defined, which may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on Pieris' proprietary platform to generate innovative immuno-oncology bispecific drug candidates. The collaboration may be expanded by up to three additional therapeutic programs. Pieris has the option, at a predefined time point, to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332, while Servier will be responsible for development and commercialization of the 4 other programs worldwide.

The financial terms of the collaboration include an upfront payment to Pieris of EUR30 million (approximately \$31.3 million USD). Pieris may also receive FTE funding for specific projects, an option fee upon potential expansion of the collaboration as well as development-dependent and commercial milestone payments for PRS-332 and each additional program. The total development, regulatory and sales-based milestone payments to Pieris could reach EUR324 million (approximately \$338 million USD) for PRS-332, and up to EUR193 million (approximately \$201 million USD) for each of the other programs. Pieris and Servier will share preclinical and clinical development costs for each co-developed program. In addition, Pieris will be entitled to receive tiered royalties up to low double digits on the sales of commercialized products in the Servier territories.

Pieris' multispecific technology allows simultaneous checkpoint inhibition on the same cell, which could have a clear advantage over monoclonal antibody cocktails against different checkpoint targets. PRS-332 is a novel PD-1-based bispecific, comprising an anti-PD-1 antibody genetically linked to an Anticalin protein targeting an undisclosed checkpoint target. Pieris has developed PRS-332, which is currently in preclinical development, with the intent to simultaneously block two immune checkpoints co-expressed on exhausted T cells to further improve on existing PD-1 therapies.

"Servier is a highly complementary partner for Pieris, with a very clear commitment to oncology and outstanding development capabilities," stated Dr. Louis Matis, Senior Vice President and Chief Development Officer of Pieris. "The synergies of building unique bispecifics from Servier's antibodies and Pieris' Anticalin proteins are multifold, as the versatility of our platform allows for extensive combinatorial target opportunities with the numerous IO 'building blocks' our team has discovered to date."

"This alliance will significantly enhance Servier's portfolio in immuno-oncology, which already comprises 5 products in late preclinical or early development. Servier's recognized expertise in drug development will efficiently complement Pieris' innovative technology, allowing both companies to bring innovative solutions to cancer patients," stated Jean-Pierre Abastado, PhD, Director of Oncology R&D at Servier.

"Servier has built a diversified and innovative portfolio in oncology that includes small molecules, engineered antibodies, and cell therapies for the treatment of both hematological malignancies and solid tumors. Today's alliance with Pieris adds another dimension to our strategy of becoming a key player in oncology, providing several next-generation bispecific IO drugs to our pipeline," added Emmanuel Canet, M.D., Ph.D., President of Servier R&D.

"Our alliance with Servier is clearly a transformative one for Pieris and is the type of partnership we deliberately set out to achieve to create significant long-term value. This collaboration provides not only an opportunity to advance multiple programs with retained rights in the number one oncology market, but also provides significant funding and flexibility for Pieris to balance financial and operational resources as we enter the next stage of corporate development," stated Stephen Yoder, President and Chief Executive Officer of Pieris. "The Servier alliance will act as a significant building block of our pipeline expansion in immuno-oncology and demonstrates the value of our proprietary Anticalin drug class."

#### **Conference Call:**

Pieris will host an investor conference call on Thursday, January 5, 2017 at 8:30 AM (EST) to discuss the collaboration. To access the call, participants may dial 1-877-407-8920 (US & Canada) or 1-412-902-1010 (International) at least 10 minutes prior to the start of the call.

An archived replay of the call will be available by dialing 1-877-660-6853 (US & Canada) or 1-201-612-7415 (International) and providing the Conference ID #13652361.

#### **About Pieris Pharmaceuticals:**

Pieris Pharmaceuticals is a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multispecifics tailored for the tumor microenvironment, an inhaled Anticalin protein to treat uncontrolled asthma and a half-life-optimized Anticalin protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin<sup>®</sup> is a registered trademark of Pieris. For more information visit www.pieris.com.

#### **About Servier:**

Servier is an international pharmaceutical company governed by a non-profit Foundation and headquartered in France. With a strong international presence in 148 countries and a turnover of 4 billion euro in 2016, Servier employs over 21,000 people worldwide. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular diseases, diabetes, cancers, immune-inflammatory diseases and neurodegenerative diseases, as well as by its activities in high quality generic drugs. Being completely independent, the Group reinvests 25% of Servier's products turnover in Research and Development, and all its profits in its growth.

Becoming a key player in oncology is part of Servier's long-term strategy. Currently, there are nine new molecular entities in clinical development in this area, targeting breast and lung cancers, and other solid tumors, as well as various leukemias and lymphomas. This portfolio of innovative cancer treatments is being developed with partners worldwide, and covers different cancer hallmarks and modalities, including cytotoxics, proapoptotics, targeted, immune, and cellular therapies, to deliver life-changing medicines to patients. For more information visit www.servier.com.

#### **About Anticalin Therapeutics:**

Anticalin proteins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalin proteins feature the typical four-loop variable region and a rigidly conserved beta-barrel backbone of lipocalins, which, together, form a shapeable cup-like binding pocket. Proprietary to Pieris, Anticalin proteins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin<sup>®</sup> is a registered trademark of Pieris.

#### **Forward Looking Statements**

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business and product development plans and timelines; the timing and progress of our studies,

development of therapeutic programs; ability to receive research funding; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; current or future partnerships; or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and the Company's Quarterly Reports on Form 10-Q.

#### **Contacts at Pieris:**

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#### **Contacts at Servier:**

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#### ##END##

#### NON-EXCLUSIVE ANTICALIN® PLATFORM TECHNOLOGY LICENSE AGREEMENT

THIS NON-EXCLUSIVE ANTICALIN® PLATFORM TECHNOLOGY LICENSE AGREEMENT ("Agreement") is made and entered into effective as of January 4, 2017 (the "Effective Date"), by and between PIERIS PHARMACEUTICALS, INC., a Nevada corporation having its principal place of business at 255 State Street, 9th floor, Boston, MA 02109 AND PIERIS PHARMACEUTICALS GMBH, a company organized and existing under the laws of Germany having offices and principal place of business at Lise-Meitner-str. 30, 85354 Freising, Germany (collectively, "Pieris"), and LES LABORATOIRES SERVIER, a corporation incorporated under the laws of France having a principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France and INSTITUT DE RECHERCHES INTERNATIONALES SERVIER, a company duly organized and existing under the laws of France, having offices and principal place of business at 50 Rue Carnot, 92284 Suresnes Cedex, France (collectively, "Licensee"). Pieris and Licensee each may be referred to herein individually as a "Party," or collectively as the "Parties."

#### RECITALS

A. Pieris Controls (defined below) certain intellectual property related to Pieris' Platform Technology (defined below).

**B.** Licensee desires to obtain from Pieris a non-exclusive license (or sublicense, as applicable) under such intellectual property to Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized, the Licensed Products in the Licensed Field and Licensed Territory (as such terms are defined below).

**C.** Pieris is willing to grant such non-exclusive license (or sublicense, as applicable) to Licensee on the terms and conditions set forth herein.

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Pieris and Licensee hereby agree as follows:

#### AGREEMENT

#### 1. **DEFINITIONS**

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

**1.1** "Accounting Standards" means the International Financial Reporting Standards, the US Generally Accepted Accounting Principles, and any other internationally recognized accounting standards that may be adopted by a Party.

**1.2** "Affiliate" means with respect to a Party, any person or entity, which directly or indirectly controls, is controlled by, or is under common control with such Party. Solely as used in this definition, the term "control" means (a) the ownership, directly or indirectly, beneficially or

# CONFIDENTIAL TREATMENT REQUESTED

legally, of at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a person or entity in a particular jurisdiction) of such Party or other person or entity, as applicable, or such other comparable ownership interest with respect to any person or entity that is not a corporation; or (b) the power, direct or indirect, whether through ownership of voting securities or partnership or other ownership interests, by contract or otherwise of more than fifty percent (50%), to direct the management and policies of a Party or such other person or entity, as applicable. Notwithstanding the foregoing, "Affiliate" shall not include entities engaged in generics or biosimilar business to the extent they do not use or access Data, Know-How or other intellectual property licensed hereunder to conduct their generics or biosimilar business; such entities shall be considered Third Parties for purposes of this Agreement.

**1.3** "Anticalin" or "Anticalin protein" means, whether in nucleic acid or protein form, (a) any lipocalin mutein isolated from the Anticalin Libraries, or (b) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin mutein referred to in Section (a) of this definition, in each case, which binds and recognizes a specific target. For the sake of this Section, mutein shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

**1.4** "Anticalin Affinity Maturation" means the process of engineering for an Anticalin protein to enhance its developability profile, such as increasing binding activities and specificity by introducing, e.g., one or more amino acid mutations.

**1.5** "Anticalin Characterization" means the assessment of binding and functional potency and/or the evaluation of the developability profile of Anticalin proteins and/or fusion proteins that include one or more Anticalin proteins.

1.6 "Anticalin Expression" means heterologous expression of an Anticalin protein in host cell.

**1.7** "Anticalin Fusion Technology" means the process of fusing one or more Anticalin proteins to an immunoglobulin or fragment thereof to create bispecific, [\*\*\*] fusion proteins.

**1.8** "Anticalin Libraries" means any phage display library based on (a) the [\*\*\*] (Uniprot [\*\*\*]) or (b) the [\*\*\*] (Uniprot [\*\*\*]).

**1.9** "Anticalin Selection" means the process of screening an Anticalin Library with a defined target through the process of phage display, within a solution, and physically separating the target, containing binding Anticalin proteins, from the solution containing non-binding Anticalin proteins.

**1.10** "Arbitration" is defined in Section 10.2.1.

1.11 "Arbitration Request" is defined in Section 10.2.1.

2

#### CONFIDENTIAL TREATMENT REQUESTED

1.12 "Audited Party" shall have the meaning set forth in Section 3.7.

1.13 "Auditing Party" shall have the meaning set forth in Section 3.7.

**1.14** "Biological License Application" or "BLA" means a Biological License Application in the United States as described in Section 351(a) of the United States Public Health Service Act (PHS Act), or an abbreviated Biological License Application as described in Section 351(k) of the PHS Act.

**1.15** "**Biosimilar**" means, with respect to a given Licensed Product in a given country of the Territory, any biological product on the market in such country that is approved (a) by the applicable Competent Authority in such country under the biosimilarity standard set forth in the United States under 42 U.S.C. §§ 262(i)(2) and (k), or any similar standard under its foreign equivalent applicable Law, on a country-by-country basis where such Licensed Product is marketed, provided that such applicable Law exists; and (b) in reliance in whole or in part, on a prior Marketing Approval (or on any safety or efficacy data submitted in support of such prior Marketing Approval) of such Product. For countries or jurisdictions where no explicit biosimilar regulations exist, Biosimilar includes products which have been deemed to be a Biosimilar or otherwise deemed interchangeable by a Competent Authority in another country or jurisdiction. Any product or component thereof (including any Licensed Product or component thereof) licensed, marketed, sold, manufactured, or produced by or on behalf of a Party, its Affiliates or Sublicensees (to the extent such Sublicensee commercializes a Biosimilar in reliance on or access to the Data, Patents and Know-How licensed under this Agreement) will not constitute a Biosimilar.

**1.16** *"Business Day"* means a day that is not a Saturday, Sunday or a day on which banking institutions in Paris, France or Munich, Germany, are authorized by applicable Law to remain closed.

**1.17** "Calendar Quarter" means each three (3) consecutive calendar months ending on each March 31, June 30, September 30 and December 31.

1.18 "Calendar Year" means any period of time commencing on January 1 and ending on the next December 31.

**1.19** "Collaboration Agreement" shall have the meaning set forth in Section 2.1.

**1.20** "**Compassionate Use**" means the use of a Licensed Product as an investigational drug (prior to Marketing Approval) in accordance with applicable Law outside of a clinical study to treat a patient with a serious or life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

**1.21** "**Commercialization**" means any and all activities of obtaining pricing and reimbursement strategy, marketing, promoting, distributing, importing, exporting, offering for sale, having sold, selling or conducting any other commercial exploitation activities relating to a Licensed Product. For clarity, "Commercialize" has a correlative meaning.

# CONFIDENTIAL TREATMENT REQUESTED

**1.22** "**Competent Authority**" means any regulatory agency, department, bureau, commission, council or other governmental entity of (a) any country, territory, national, federal, state, provincial, county, city or other political subdivision government, including the FDA, or (b) any supranational body (including the EMA), in any applicable jurisdiction in the world, involved in the granting of Marketing Approval.

**1.23 "Control"** means, with respect to any patent, know-how or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or to grant a license, sublicense or other right to or under, such patent, know how or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party.

**1.24** "Cover", "Covered" or "Covering" means, with respect to the applicable invention, discovery, process or product (including a Licensed Product), as appropriate, (a) a Patent, that, in the absence of a (sub)license under, or ownership of, such Patent, the Development, Manufacture or Commercialization of such invention, discovery, process or product (including making, using, offering for sale, selling or importing thereof), as appropriate, with respect to a given country, would infringe a Valid Claim of such Patent (or, in the case of a Patent that has not yet issued, would infringe any then-pending Valid Claim in such Patent if it were to issue with such claim), or (b) any Know-How, that, in the absence of a (sub)license under, or ownership of, such Know-How, the Development, Manufacture or Commercialization (including making, using, offering for sale, selling or importing thereof) of such invention, discovery, process or product incorporates, embodies or otherwise makes use of such Know-How.

**1.25** "*Data*" means any and all non-aggregated and aggregated research, pharmacology, pre-clinical, clinical, commercial, marketing, process development, manufacturing and other data or information, including investigator brochures and reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety data, in each case generated from, or related to, Clinical Studies or non-clinical studies, research or testing specifically related or directed to a Licensed Product.

**1.26** "Development" means with respect to a Licensed Product, all research, and all pre-clinical, non-clinical and clinical research and development activities performed to obtain and maintain the Marketing Approval for the relevant Licensed Product, including without limitation: test method development and stability testing, assay development, translational research, toxicology, pharmacology, formulation, quality assurance, quality development, statistical analysis, CMC, process development, and scale-up, pharmacokinetic studies, data collection and management, Clinical Studies (including research to design Clinical Studies and specifically excluding activities directed to obtaining pricing and reimbursement approvals), regulatory affairs (including submission of Data or other materials to a Competent Authority to obtain, maintain and/or expand Marketing Approval of a Licensed Product), project management, drug safety surveillance activities related to Clinical Studies, validation of methods and tests. For Clarity, "Develop" and "Developing" have a correlative meaning.

1.27 "Disclosing Party" is defined in Section 6.1.

4

**1.28** "Dispute" is defined in Section 10.2.1.

**1.29** "First Commercial Sale" means the first sale to a Third Party of a Licensed Product by or under the authority of Licensee or its Affiliates or Sublicensees, in a country after receipt of the applicable Marketing Approval, as desirable in such country, from the Competent Authorities in that country. For the avoidance of doubt, Compassionate Use shall not be considered a First Commercial Sale.

**1.30** "GLP Tox Study" means, with respect to a Licensed Product, a study conducted in a species using applicable regulatory good laboratory practices for the purposes of assessing the safety and the onset, severity, and duration of toxic effects and their dose dependency with the goal of establishing a profile required for obtaining an IND/IMPD. For the avoidance of doubt, preliminary toxicology studies are not regarded as a GLP Tox Study.

**1.31** "Government Authority" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other government instrumentality of (a) any country, territory, nation, state, province, county, city or other political subdivision thereof or (b) any supranational body, including any Competent Authority.

1.32 "Indemnitee" means either a Licensee Indemnitee or a Pieris Indemnitee.

**1.33** "**IND/IMPD**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, (b) the Investigational Medicinal Product Dossier in the applicable European territories, or (c) the equivalent application to the applicable Competent Authority in any other regulatory jurisdiction, and any amendments to the foregoing (a), (b) or (c), in each case, the filing of which is necessary to initiate or conduct clinical testing of an investigational drug or biological product in humans in such jurisdiction.

**1.34** "Indication" means a distinct type of disease or medical condition in humans to which a Licensed Product is directed and eventually approved. To distinguish one Indication from another Indication, the two Indications have to be (a) listed in two different blocks of the ICD-10 (chapter II, Neoplasms, version 2016) (as a way of example, any neoplasm under C15 is in a different block from any neoplasm under block C16, whereas C15.0 and C15.1 belong to the same block) and (b) developed under one or more separate Clinical Studies. Notwithstanding the foregoing, small-cell lung cancer and non-small cell lung cancer shall be deemed to be two distinct Indications and colon and rectal cancer (colorectal cancers); all cancers of the head and neck sphere (mouth, larynx, pharynx, sinuses, salivary glands, and tongue); and cancers of the renal pelvis, bladder, urethra, and ureter (urothelial cancers) shall be considered as one Indication.

**1.35 "Know-How"** means any and all ideas, concepts, designs, technical information, techniques, Data, database rights, discoveries, inventions, practices, methods, procedures, processes, methods, algorithm, knowledge, skill, experience, test data and any other information or technology, whether in written, electronic, graphic or any other form, including pharmaceutical, chemical, biological and biochemical compositions, formulations, assays, APIs, molecules, samples, cell lines, journals and laboratory notebooks.

#### **1.36** "Licensee Indemnitees" is defined in Section 8.2.

**1.37** "Licensed Field" means, on a Licensed Product-by-Licensed Product basis, the permissible field of use under the Collaboration Agreement.

**1.38** "Licensed Product" means any product that includes at least one Anticalin protein, including any fusion protein that includes one or more Anticalin proteins.

**1.39** "Licensed Territory" or "Territory" means, on a Licensed Product-by-Licensed Product basis, the territory licensed to the Licensee under the Collaboration Agreement.

**1.40** "Manufacture" means, with respect to a Licensed Product, all activities related to the manufacture of the Licensed Products, including, but not limited to, manufacturing supplies for Development or Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, shipment, import and export as needed, improvement of production, improvement of manufacturing processes, and regulatory activities related to any of the foregoing. For clarity, "Manufacturing" has a correlative meaning.

**1.41** "Marketing Approval" means all approvals, licenses, registrations or authorizations of the Competent Authorities in a country, necessary for the commercial marketing and sale of the Licensed Product in such country, including the approval of a MAA or a BLA.

**1.42** "Law" means any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any applicable Government Authority, including any rules, regulations, guidelines, directives or other requirements of applicable Government Authorities, including good clinical practices, good laboratory practices and good manufacturing practices, as well as all anti-bribery or anti-corruption laws, as applicable.

**1.43** "Losses" is defined in Section 8.1.

**1.44** "Net Sales" means, in the case of sales by or for the benefit of Licensee, its Affiliates, and its Sublicensees (in each case, "*Seller*") in the Territory to a Third Party, the gross amount of monies invoiced by Seller with respect to the Products, less the following deductions ("*Permitted Deductions*"):

(a) trade, cash, promotional and quantity discounts to the extent actually given;

(b) taxes on sales (such as excise, sales or use taxes or value added tax), but excluding any taxes on Seller's income;

(c) customary freight, insurance, packing costs and other transportation charges added to the sales price that are incurred in delivering the Product;

6

(d) amounts repaid or credits taken by reason of rejections, defects or returns or because of retroactive price reductions, or due to recalls or applicable Laws requiring rebates;

(e) free good, rebates taken by or distribution fees paid to distributors, and charge-backs;

(f) customs duties actually paid by Seller on import into the country of sale to the extent invoiced and not otherwise reimbursed;

(g) rebates and/or discounts on sales of Licensed Products given to health insurance and other types of payers in any given country of the Territory due to specific agreement ("claw-back" type of agreements) with respect to the Licensed Products;

(h) the actual amount of any write-offs for bad debt in accordance with the standard practices of Seller for writing off uncollectible amounts consistently applied; provided with respect to such write-off that an amount subsequently recovered or reversed with respect to such write-off will be treated as Net Sales in the quarter in which it is recovered or reversed; and

(i) any other specifically identifiable amounts included in gross amounts invoiced for the Licensed Products, to the extent such amounts are customary deductions from net sales calculations in accordance with IFRS as consistently applied by Licensee, its Affiliates, and its Sublicensees for reporting their respective net sales.

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in clauses (a)-(i) above, such item may not be deducted more than once.

"*Net Sales*" shall not include any consideration received with respect to a sale, use or other disposition of any Licensed Product in a country for purposes of conducting Clinical Studies in the course of Development of the Licensed Product in accordance with this Agreement or as samples (reasonable in number) or for Compassionate Use, in each case provided that Seller does not receive consideration of monetary value for such Licensed Products. Notwithstanding the foregoing, the amounts invoiced by Licensee, its Affiliates, or their Sublicensees for the sale of Product among Licensee, its Affiliates or their respective Sublicensees for resale shall not be included in the computation of Net Sales hereunder (except where such Affiliates or Sublicensees are the end users) and Net Sales shall be the gross invoice or contract price charged to the Third Party customer for that Licensed Product in an arms' length transaction, less the Permitted Deductions. Net Sales calculations shall be determined in accordance with Accounting Standards consistently applied throughout the organization and across all products of the entity whose sales of Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Licensed Product in the country of sale or transfer, as determined in accordance with Accounting Standards consistently applied (as contemplated above).

7

#### CONFIDENTIAL TREATMENT REQUESTED

In the case where a Licensed Product is sold as part of a Combination Product in a country in the Territory, Net Sales for the Licensed Product included in such Combination Product in such country shall be calculated as follows:

(i) if the Licensed Product is sold separately in such country and the other active ingredient or ingredients in the Combination Product are sold separately in such country, Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the invoice price of the Licensed Product when sold separately in such country and B is the total invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country;

(ii) if the Licensed Product is sold separately in such country but the other active ingredient or ingredients in the Combination Product are not sold separately in such country, Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the invoice price of the Licensed Product when sold separately in such country and D is the invoice price of the Combination Product in such country;

(iii) if the Licensed Product is not sold separately in such country but the other active ingredient or ingredients in the Combinations Product are sold separately in such country, Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction 1 - (B/D), where B is the invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country and D is the invoice price of the Combination Product in such country; or

(iv) if neither the Licensed Product nor the other active ingredient or ingredients in the Combination Product are sold separately in such country, the Parties shall determine Net Sales for the Licensed Product in such Combination Product by mutual agreement based on the relative contribution of the Licensed Product and each other active ingredient to the Combination Product, and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

For purposes of this Section 1.44, "**Combination Product**" means a product that includes at least one active ingredient other than a Licensed Product, when a single sale or reimbursement price is set for such Combination Product.

**1.45 "Patents"** means any and all patent rights and all right, title and interest in all patent applications and patents that issue from them, all letters patent or equivalent rights and applications in each case to the extent the same has not been held, by a court of competent jurisdiction, to be invalid or unenforceable in a decision from which no appeal can be taken or from which no appeal was taken within the time permitted for appeal. Patents include any extension, registration, confirmation, reissue, continuation, supplementary protection certificate, divisional, continuation-in-part, re-examination or renewal thereof or foreign counterparts of any of the foregoing.

**1.46** "**Phase 1 Clinical Study**" means a clinical study of a product in human subjects which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, as described in 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).

8

# CONFIDENTIAL TREATMENT REQUESTED

**1.47** "**Phase 1 Clinical Study Expansion Cohort**" means the expansion of a Phase 1 Clinical Study to include additional patient(s) following the selection of a dose during the dose escalation part of the Phase 1 Clinical Study (such as a maximum tolerated dose).

**1.48** "Phase 2 (2a and/or 2b) Clinical Study", "Phase 2a Clinical Study" or "Phase 2b Clinical Study" means a clinical study of a product that is prospectively designed to establish the safety, dose ranging and efficacy of a product as further defined in 21 C.F.R. § 312.21(b) (or the non -United States equivalent thereof).

**1.49** "**Pivotal Clinical Study**" means a clinical study of a product that is designed to generate statistically significant evidence of the efficacy of a product for a particular Indication or use (as well as additional safety information) and that is intended to form the primary scientific support for filing a BLA to obtain Marketing Approval to market the product, (or any MAA for the non-United States equivalent thereof).

**1.50** "Pieris Indemnitees" is defined in Section 8.1.

**1.51** "Platform Improvement IP" means any and all Know-How created, invented or generated by or on behalf of employees, agents, or independent contractors of either Party or their Affiliates (whether alone or jointly) in the course of performing activities pursuant to this Agreement or the Collaboration Agreement that constitutes an improvement, modification or enhancement to, or derivative of, the Platform IP, including any intellectual property rights deriving therefrom.

1.52 "Platform IP" means the Platform Know-How and the Platform Patents.

**1.53** "**Platform Know-How**" means Know-How Controlled by Pieris on the date hereof and during the Term that are necessary or useful for the practice of the Platform Technology, including all Know How within the Platform Improvement IP.

**1.54** "**Platform Patents**" means those Patents Controlled by Pieris on the date hereof and during the Term directed to the Platform Technology, including all Patents within the Platform Improvement IP. A list of Platform Patents as of the date hereof is attached as <u>Exhibit A</u> hereto and will be updated by Pieris as required from time to time during the Term.

**1.55** "**Platform Technology**" means Anticalin Libraries, Anticalin Selection, Anticalin Expression, Anticalin Characterization, Anticalin Fusion Technology, and Anticalin Affinity Maturation methods, all to the extent Controlled by Pieris.

**1.56** "Collaboration Agreement" is defined in Section 2.1.

**1.57** "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any applicable Competent Authority, other than an issued and unexpired Patent, including any regulatory data protection exclusivity (including, where applicable, pediatric exclusivity and/or orphan drug exclusivity) and/or any other exclusivity afforded by restrictions which prevent the granting by a Competent Authority of regulatory approval to market a Biosimilar.

9

# CONFIDENTIAL TREATMENT REQUESTED

**1.58** "**Royalty Term**" means, on a country-by-country basis and a Licensed Product-by- Licensed Product basis, the period commencing on the First Commercial Sale of the Licensed Product in a country and ending with respect to such Licensed Product in such country on the later of (a) ten (10) years thereafter in such country; (b) last to expire Regulatory Exclusivity relating to such Licensed Product; or (c) expiration of the last to expire Valid Claim of any Platform Patent in each case, Covering such Licensed Product in such country [\*\*\*].

- **1.59** "Rules" is defined in Section 10.2.1.
- **1.60** "Sublicensee" is defined in Section 2.2.
- **1.61** "Term" it is defined in Section 7.1.
- 1.62 "Third Party" means any party other than Pieris, Licensee, or their respective Affiliates.
- **1.63** "Third Party Claims" is defined in Section 8.1.
- **1.64** "[\*\*\*]" means that certain [\*\*\*].

**1.65 "Valid Claim"** means (a) a claim of an issued and unexpired Platform Patent, which claim has not been revoked or held invalid or unenforceable by a court or other government agency of competent jurisdiction by a determination or has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity suit or otherwise by a determination or (b) a claim of a pending Platform Patent application that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling; provided, however, that Valid Claim will exclude any such pending claim in an application that has not been granted within [\*\*\*] years following the earliest priority filing date for such application. For purposes of the definition of Valid Claim, "determination" means a determination with respect to a Platform Patent that would prevent a Party from enforcing or continuing to enforce such Platform Patent. To the extent that any Platform Patent is issued, restored or otherwise deemed valid and enforceable, then it once again shall be considered a Valid Claim as from the date of such issuance, restoration or determination.

**1.66** "Withholding Taxes" is defined in Section 3.6.3.

#### 2. LICENSE GRANT

2.1 Grant. Subject to the terms and conditions of this Agreement, Pieris hereby grants to Licensee a non-exclusive, non-transferrable (other than in accordance with Section 10), royalty-bearing license (or sublicense) during the Term under the Platform IP and the Platform Improvement IP, to Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized, the Licensed Products in the Licensed Field and Licensed Territory pursuant to and consistent with that certain separate written agreement entitled License and Collaboration Agreement entered into on the date hereof and in effect and in good standing between Pieris and Licensee (such agreement, the "Collaboration Agreement").

10

#### 2.2 Sublicenses.

**2.2.1** Licensee shall have the right to grant sublicenses under the rights granted in Section 2.1 (a) to its Affiliates and (b) to Third Parties, in each of (a) and (b) solely to the extent of, and consistent with, Licensee's right to grant sublicenses of any Patent rights under the applicable Collaboration Agreement. Each such sublicense granted pursuant to this Section 2.2 shall be pursuant to a binding written agreement and shall be consistent with the terms and conditions of this Agreement (including imposing obligations on Sublicensee consistent with those of Licensee under Sections 2.3, 3.7 and Section 6) and the applicable Collaboration Agreement (each such Affiliate or Third Party to which such sublicense is granted, a "**Sublicensee**"). Licensee shall remain responsible for the performance of its Sublicensees such that any act or omission by or on behalf of a Sublicensee that would be a breach of this Agreement if undertaken by Licensee, shall be deemed a breach of this Agreement by Licensee. In the event of a material default by any Sublicensee will promptly notify Pieris and take such action as necessary to remedy such default.

**2.2.2** With respect to any (sub) license agreement(s) entered into with a Sublicensee by Licensee in effect as of the date at which termination or expiration of this Agreement becomes effective and the Sublicensee's rights under such Sublicense, to the extent that the Sublicensee is in good standing with respect to the Sublicense and was not itself the cause of the termination of this Agreement, Pieris shall negotiate in good faith a direct license with the Sublicensee under the following terms and conditions (provided that such Sublicensee's election to terminate the Sublicensee): (1) the Parties shall negotiate such direct license in good faith in order to execute a direct license within [\*\*\*] of the termination or expiration of this Agreement, (2) such direct license shall have the same scope, payment and financial terms and non-financial terms as this Agreement, and (3) such direct license to the Sublicensee by Pieris shall not place any additional obligations (including but not limited to representations, warranties, or liabilities) on Pieris beyond its obligations under this Agreement without the prior written consent of Pieris.

2.3 No Other License. Licensee understands and agrees that no license under any patent, patent application or know-how other than Platform Patents and Platform Know-How, is or shall be deemed to have been granted under this Agreement, either expressly or by implication. Licensee shall not practice under the Platform Patents or Platform Know-How outside of the scope of the license granted pursuant to Section 2.1 of this Agreement.

#### 3. PAYMENTS

**3.1** License Fee. In partial consideration of the rights granted hereunder with respect to up to five (5) Licensed Products, Licensee shall pay to Pieris a non-creditable, non-refundable upfront fee in the amount of [\*\*\*] following receipt of the corresponding invoice from Pieris after the Effective Date.

11

# CONFIDENTIAL TREATMENT REQUESTED

**3.2** Additional License Fee. In the event that Licensee exercises an option to include up to three (3) additional Licensed Products under the Collaboration Agreement, in partial consideration thereof, Licensee shall pay to Pieris a non-creditable, non-refundable upfront fee in the amount of [\*\*\*] following receipt of the corresponding invoice from Pieris after the Effective Date.

**3.3** Milestone Payments. Licensee will pay to Pieris the following milestone payments upon the first achievement of the corresponding milestone event set forth in the table below by or on behalf of Licensee, its Affiliates and Sublicenses, on a Licensed Product-by-Licensed Product basis:

Milestone Event	<b>Milestone Payment</b>
Start of the in-life phase in a GLP Tox Study	[***]
First dosing of the first patient in a Phase 1 Clinical Study	[***]
First dosing of the first patient in a Phase 2a Clinical Study or Phase 1 Clinical Study Expansion Cohorts	[***]
First dosing of the first patient in a Pivotal Clinical Study	[***]
Marketing Approval in [***]	[***]

<u>Milestone Payment Terms</u>. Each such milestone payment shall be paid within [\*\*\*] of achievement of such milestone event by Licensee or its Sublicensee. For any Licensed Product, once a milestone is reached, the amounts under all prior milestones shall be due, if not yet paid (for example, if a Pivotal Clinical Study is initiated and the Phase 2a Clinical Study or Phase 1 Clinical Study Expansion Cohorts milestone has not yet been paid, it shall become due and payable at the same time as the Pivotal Clinical Study milestone).

**3.4** Royalties. Within [\*\*\*] after the end of each Calendar Quarter following the First Commercial Sale of Licensed Product, Licensee shall make royalty payments to Pieris on a Calendar Quarter and Licensed Product-by-Licensed Product basis, based on the Net Sales of the applicable Licensed Product by Licensee and its Sublicensees at a rate of [\*\*\*] (the "Royalties"). Royalties shall be payable by Licensee until the expiry of the Royalty Term.

The royalties due under this Section 3.4 will be determined based on quarterly Net Sales in a given Calendar Year. Each payment of royalties shall be accompanied by a written report setting forth the amount of Licensee's and its Sublicensees' gross receipts, Net Sales, and all deductions and allowances taken from gross receipts to arrive at Net Sales (to the extent contemplated by the definition of Net Sales); and the royalty payment then due during such Calendar Quarter, containing reasonable detail on a country-by-country basis, regarding the calculation of the royalties and the underlying sales data.

12

#### 3.5 Adjustments.

**3.5.1** <u>Biosimilar Drug Competition</u>. Notwithstanding the foregoing, subject to Section 3.5.3, if in any Calendar Quarter total sales of any Biosimilar(s) of a Licensed Product in any country reaches more than [\*\*\*] in [\*\*\*] of the [\*\*\*] of the applicable Licensed Product and the Biosimilar(s) in such country, then (a) the Royalties payable to Pieris for such Licensed Product in such country shall be reduced by [\*\*\*] of the amount otherwise payable hereunder and (b) beginning [\*\*\*] years from the First Commercial Sale of the Licensed Product in such country and thereafter, no further Royalties shall be due for such Licensed Product in such country. Notwithstanding the foregoing, in the event of Biosimilar sales that are later enjoined by a court or otherwise halted (such as on the basis of patent or regulatory exclusivity), then subsequent royalties shall be restored to the level otherwise contemplated under this Agreement.

**3.5.2** Third Party Licenses. If it is reasonably necessary for Licensee (including as evidenced by an opinion of internationally recognized outside counsel) to license one or more Patents from one or more Third Parties in order to Develop, Manufacture (other than manufacturing processes), Commercialize or use the drug substance of any Licensed Product (due to, for example, the polypeptide sequence or targets of such Licensed Product but excluding, for example, formulation Patents or Manufacturing process Patents), whether directly or through any Affiliate or Sublicensee, in the Territory, then Licensee may negotiate and obtain a license under such Patent(s) (each such Third Party License or in the context of proceedings brought by any Third Party due to one or more Patent(s) of such Third Party is infringed by the Development, Manufacture (other than manufacturing processes), Commercialization or use of the drug substance of any Licensed Product in the Field under this Agreement, then subject to Section 3.5.3 Licensee may deduct [\*\*\*] of such payment(s) from the Royalties associated to such Licensed Product otherwise payable under Section 3.4, but in no event shall Royalties be reduced by greater than [\*\*\*] under this Section 3.5.2. For avoidance of doubt, this Section does not limit either Party's right to obtain any Third Party License as it may deem necessary or useful.

**3.5.3** <u>Maximum Deduction</u>. Notwithstanding anything to the contrary herein, under no circumstances shall the combined effect of all reductions to the Royalties permitted under Sections 3.5.1 and 3.5.2, on a country-by-country and Licensed Product-by-Licensed Product basis, reduce the effective Royalties payable by Licensee to Pieris under this Agreement for any Calendar Quarter below [\*\*\*] of the Royalties that would otherwise be payable pursuant to Section 3.4, as applicable, for such Licensed Product in such country.

**3.5.4** <u>Other Adjustments</u>. In the event that Pieris is found to have breached this Agreement under Section 10.2.1, then the royalties due to Pieris under this Section 3 shall be reduced by [\*\*\*].

13

#### 3.6 Payment Terms.

**3.6.1** <u>Generally</u>. After the First Commercial Sale by the Seller of a Licensed Product requiring the payments due to Pieris pursuant to Section 3.4 and ending, on a Licensed Product-by-Licensed Product basis, following the last to expire Royalty Term with respect to such Licensed Product, Licensee shall send to Pieris within [\*\*\*] after the end of each Calendar Quarter (a) a written report which shall state, for the previous Calendar Quarter, on a country-by-country and Licensed Product-by-Licensed Product basis, the description of each Licensed Product sold, the corresponding amount of gross sales of Licensed Products, an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales and the calculation of any milestones fees and Royalties due, including any reductions made in accordance with this Agreement, as well as the exchange rate for such country, and (b) payment (in Euros) all royalty payments due to Pieris hereunder for such Calendar Quarter.

**3.6.2** <u>Interest</u>. Interest shall accrue on any late payment of fees owed to Pieris not made on the date such payment is due, at an annual interest rate equal to the lesser of (a) the Euribor one month with respect to payments in Euros plus [\*\*\*] or (b) the highest rate permissible by Law, with such interest accruing from the date the payment was originally due to Pieris.

**3.6.3** Taxes and Withholding. All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this Section 3.6.3, the Parties agree to cooperate with one another and use reasonable efforts to minimize under applicable Law obligations for any and all income or other taxes required by applicable Law to be withheld or deducted from any of the royalty and other payments made by or on behalf of a Party hereunder ("Withholding Taxes"). The Licensee shall, if required by applicable Law, deduct from any amounts that it is required to pay to Pieris an amount equal to such Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for Pieris's account and, if available, evidence of such payment shall be secured and sent to Pieris within [\*\*\*] of such payment. The Licensee shall, at Pieris's sole cost and expense, as mutually agreed by the Parties, do all such lawful acts and things and sign all such lawful deeds and documents as Pieris may reasonably request to enable the Licensee to avail itself of any applicable legal provision or any double taxation treaties with the goal of paying the sums due to Pieris hereunder without deducting any Withholding Taxes.

**3.6.4** <u>Conversions</u>. With respect to amounts required to be converted into another currency for calculation of the Net Sales amount, the milestones and the Royalty payments, such amount shall be converted using a rate of exchange which corresponds to the average quarterly rate published by the European Central Bank as used by Licensee for conversion between the relative currencies for its reporting period in its books and records that are maintained in accordance with Accounting Standards, as applicable, for its external reporting.

**3.7 Records Retention**. Licensee shall keep complete, true and accurate books of account and records for the purpose of determining the amounts payable under this Agreement.

14

# CONFIDENTIAL TREATMENT REQUESTED

Such books and records shall be kept at the principal place of business of Licensee, as the case may be, for at least [\*\*\*] years (or such longer period as required by applicable Law) following the end of the Calendar Year to which they pertain. Each Party (the "Audited Party") shall make such account and records available, on reasonable notice sent by the other Party (the "Auditing Party"), for inspection during normal business hours, with not less than thirty (30) Business Days' advance written notice, by an independent certified public accounting firm nominated by such and reasonably acceptable for the Audited Party, for the purpose of verifying the accuracy of any statement or report given by the Audited Party and to verify the accuracy of the payments due hereunder for any Calendar Year. Such auditor shall advise the Parties simultaneously promptly upon its completion of its audit whether or not the payments due hereunder have been accurately recorded, calculated and reported, and, if not, then the amount of such discrepancy. A Party's financial records with respect to a given period of time shall only be subject to one (1) audit per Calendar Year except in the case of willful misconduct or fraud. The Auditing Party's right to perform an audit pertaining to any Calendar Year shall expire [\*\*\*] years after the end of such Calendar Year. The auditor shall be required to keep confidential all information learnt during any such inspection, and to disclose to the Auditing Party only such details as may be necessary to report the accuracy of the Audited Party's statement or report. The Auditing Party shall be responsible for the auditor's costs, unless the auditor certifies that there was a variation or error of underpayment or overpayment exceeding [\*\*\*] of the amount stated for any period covered by the inspection, then all reasonable costs relating to the inspection for such period. If such accounting firm correctly identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be paid/refunded promptly but in any event within [\*\*\*] of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties.

#### 4. PATENT PROSECUTION, MAINTENANCE AND ENFORCEMENT

As between the Parties, Pieris shall be solely responsible, at its sole discretion and expense, for the prosecution, defense, and maintenance of Platform Patents. Licensee shall not be permitted to enforce the Platform Patents without the written consent of Pieris, which may be withheld for any reason.

#### 5. **REPRESENTATION AND WARRANTIES; COVENANTS**

5.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that, as of the Effective Date:

**5.1.1** Corporate Existence and Power. It is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is exists, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated by this Agreement, including the right to grant the rights granted hereunder.

**5.1.2** Authority and Binding Agreement. (a) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action required to authorize the execution and delivery of the

15

# CONFIDENTIAL TREATMENT REQUESTED

Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

**5.2** Further Representations by Pieris. Pieris hereby represents and warrants that it has not entered into any agreement with any Third Party that is in conflict with the rights granted to Licensee under this Agreement and covenants that during the Term it shall not enter into any agreement with a Third Party that would materially conflict with the rights granted to Licensee under this Agreement.

**5.3 DISCLAIMER OF WARRANTY.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 5.1 AND 5.2 AND THOSE SET FORTH IN THE COLLABORATION AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY HEREBY DISCLAIMS, ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, ENFORCEABILITY, PATENTABILITY, SCOPE AND NON-INFRINGEMENT AND ANY WARRANTY ARISING OUT OF PRIOR COURSE OF DEALING AND USAGE OF TRADE.

#### 6. CONFIDENTIALITY; PUBLICITY

**6.1** Neither Party shall disclose any of the terms of this Agreement (including the financial terms) to any Third Party without the prior written consent of the other Party; provided, however, that each Party shall be free to disclose the terms of this Agreement (a) to the extent that a Party reasonably believes it is required to do so by securities or other applicable laws, regulations, or rules (including the regulations or rules of any relevant stock exchange), (b) pursuant to a legal proceeding or order of a court or governmental agency, (c) to actual or prospective Sublicensees, (d) to [\*\*\*] (in the case of [\*\*\*]), (e) to its accountants, attorneys and other professional advisors, (f) to its Affiliates or (g) in connection with a financing, merger, consolidation, acquisition or a permitted assignment of this Agreement, provided that in the case of any disclosure under (c), (d), (e), (f) or (g) above, the recipient(s) are obligated and do so undertake to keep such terms of this Agreement confidential to the same extent as said Party, and provided that in the case of disclosure under clause (a) the disclosing Party will use reasonable efforts to obtain confidential treatment for portions of this Agreement as available, consult with the other Party, and permit the other Party to participate, to the extent practicable, in seeking a protective order or other confidential treatment and in the case of disclosure under clause (b) the Disclosing Party will use reasonable efforts to secure confidential treatment of such terms of this Agreement as are required to be disclosed.

6.2 Publicity. Neither Party shall issue any press release or other publicity material or make any public representation that refers to the terms, including, without limitation, the financial terms, of this Agreement without the prior written consent of the other Party.

16

#### CONFIDENTIAL TREATMENT REQUESTED

# 7. TERM AND TERMINATION

**7.1** Term. This Agreement will commence on the Effective Date and remain in full force and effect until the expiration of all of Licensee's payment obligations under this Agreement (the "Term"), unless earlier terminated in accordance with this Article 7. Following the natural expiration of the Term, the license granted to Licensee shall be fully paid up, irrevocable, and royalty-free. In addition, on a Licensed Product-by-Licensed Product and country-by-country basis, this Agreement shall terminate upon termination of the Collaboration Agreement.

7.2 Termination for Material Breach. Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or materially defaulted in the performance of any of its payment obligations hereunder which breach or default is material in the overall context of the Agreement, and such breach has continued for hundred and twenty (120) days after written notice thereof was provided to the breaching Party by the non-breaching Party which clearly describes the remedies that the non-breaching Party intends to apply should the breach remain uncured. Any such termination shall become effective at the end of such hundred and twenty (120) day period if, prior to the expiration of the hundred and twenty (120) day period, the breaching Party has not cured any such breach or default. If the allegedly breaching Party disputes the breach and provides written notice of that dispute to the other Party, the matter shall be addressed under the dispute resolution provisions in Section 10.2 and the notifying Party may not terminate this Agreement until it has been finally determined under Section 10.2 that the Agreement was materially breached as described above. The non-breaching Party will have the right to terminate this Agreement with respect to either the entire Licensed Product or only the countries to which the uncured material breach relates, provided that this Agreement cannot be terminated only with respect to some (but not all) countries of the European Union.

**7.3** Effect of Termination. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination, including Licensee's obligations to pay all fees and royalties that shall have accrued hereunder prior to the effective date of expiration or termination. Termination of this Agreement shall result in the termination of the licenses granted to Licensee, and all such rights shall immediately revert to Pieris in full. The provisions of Sections 1 (to the extent necessary to give effect to the surviving provisions), 3.8 (for any final reports), 6, 7, 8, 9 and 10 will survive any termination or expiration of this Agreement.

#### 8. INDEMNIFICATION AND INSURANCE

**8.1 Indemnification by Licensee.** Licensee will indemnify Pieris, its Affiliates, and their respective directors, officers, employees and agents (collectively, the "**Pieris Indemnitees**"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all liability suits, investigations, claims or demands by Third Parties (collectively, "**Third Party Claims**") arising out of (a) a Licensee Indemnitee's negligence or willful misconduct; or (b) Licensee's breach (or allegation of a breach) of any obligation, representation, warranty or covenant in this Agreement, except to the extent that such Losses arise out of or result from (i) the negligence or willful misconduct of a Pieris's breach of any obligation, representation, warranty or covenant in this Agreement.

17

# CONFIDENTIAL TREATMENT REQUESTED

**8.2 Indemnification by Pieris.** Pieris will indemnify Licensee and its Sublicensees, and their respective directors, officers, employees and agents (collectively, the "Licensee Indemnitees"), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of or in connection with (a) a Pieris Indemnitee's negligence or willful misconduct or (b) Pieris's breach (or allegation of a breach) of any obligation, representation, warranty or covenant in this Agreement, except to the extent that such Losses arise out of or result from (i) the negligence or willful misconduct of a Licensee Indemnitee, or (ii) Licensee's breach of any obligation, representation, warranty or covenant in this Agreement.

**8.3** Indemnification Procedure. To be eligible to be indemnified as described in this Article 8, each of the Indemnitees seeking to be indemnified shall provide the indemnifying Party with prompt notice of any claim (with a description of the claim and the nature and amount of any such loss) giving rise to the indemnification obligation pursuant to Section 8.1 or 8.2, as the case may be, and the exclusive ability to defend such claim (with the reasonable cooperation of the Indemnitee(s)). Each Indemnitee shall have the right to retain its own counsel, at its own expense, if representation by the counsel of the indemnifying Party would be inappropriate due to actual or potential differing interests between such Indemnitee(s) and the indemnifying Party. Neither the Indemnitee(s) nor the indemnifying Party shall settle or consent to the entry of any judgment with respect to any claim for losses for which indemnification is sought without the prior written consent of the other (not to be unreasonably withheld or delayed).

**8.4 Insurance.** Licensee will, and will cause its Sublicensees to, have and maintain such types and amounts of liability insurance (including product liability coverage) as is normal and customary in the industry generally for a party similarly situated, and will upon Pieris's request provide Pieris with a copy of such policies of insurance in that regard, along with any amendments and revisions thereto.

#### 9. LIMITATION OF LIABILITY

IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS OR LOSS OF DATA, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT. THE FOREGOING LIMITATIONS WILL NOT APPLY TO AN AWARD OF ENHANCED DAMAGES AVAILABLE UNDER APPLICABLE INTELLECTUAL PROPERTY LAWS FOR WILLFUL INFRINGEMENT AND WILL NOT LIMIT EITHER PARTY'S OBLIGATIONS TO THE OTHER PARTY UNDER SECTIONS 6 AND 8 OF THIS AGREEMENT.

#### **10. MISCELLANEOUS**

**10.1 Restrictions; No Other Licenses.** Except as expressly set forth hereunder, neither Party grants to the other Party any rights, licenses or covenants in or to any Patents or Know-How, whether by implication, estoppel, vicariously, indirectly or otherwise, other than the license rights

18

# CONFIDENTIAL TREATMENT REQUESTED

that are specifically and expressly granted under this Agreement. All rights not specifically and expressly granted by a licensing party under this Agreement are reserved by such licensing party and may be used or practiced by such licensing party for any purpose.

#### 10.2 Dispute Resolution

Arbitration. In the event a dispute arises (each, a "Dispute"), the Parties will attempt in good faith to resolve 10.2.1 such Dispute, failing which either Party may cause such Dispute to be referred to the Executive Officers for resolution. The Parties shall attempt in good faith to resolve such Dispute by unanimous consent. If the Parties cannot resolve such Dispute within [\*\*\*] of the matter being referred to them, then either Party may submit such Dispute to arbitration for final resolution by arbitration request (the "Arbitration Request") under the Rules of Arbitration of the International Chamber of Commerce (the "Rules") by three (3) arbitrators appointed in accordance with the said Rules (each such arbitration, an "Arbitration"). Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be Zurich, Switzerland. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrators. For purposes of Article 6(4) of the Rules, the Parties agree that claims arising out of or in connection with this Agreement and the Collaboration Agreement may be determined together in a single arbitration. For purposes of Article 10 of the Rules, the Parties agree that any Party may request the consolidation of any arbitration subject to this Agreement with any arbitration subject to the Collaboration Agreement, even if the parties to the respective arbitrations are not identical. Unless the Parties subsequently agree otherwise, the arbitrations shall be consolidated into the arbitration that commenced first.

**10.2.2** <u>Confidentiality</u>. Except to the limited extent necessary to comply with applicable Law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrators' award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

**10.2.3** <u>Communications with Internal Counsel</u>. In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon the members of its internal legal department to provide advice to such Party and its directors, employees and agents on legal matters. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

19

# CONFIDENTIAL TREATMENT REQUESTED

**10.3** Governing Law. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the Laws of [\*\*\*], excluding its rules of conflict of laws.

**10.4 Assignment.** This Agreement will not be assignable by either Party, nor may either Party delegate its obligations or otherwise transfer any licenses granted herein or other rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Party hereto, which consent will not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, each Party may assign this Agreement, without the consent of the other Party, to an Affiliate or to its Third Party successor in connection with a merger, consolidation, sale of all or substantially all of the assets to which this Agreement), or any Change of Control of such Party; provided that the assignee assumes all of the assigning Party's obligations under this Agreement, subject to this <u>Section 10.4</u>. Any assignment in violation of this provision is void and without effect.

**10.5** Trade names and Trademarks. Except as otherwise provided herein, no right, express or implied, is granted to a Party by this Agreement to use in any manner the name of the other Party or its Affiliates or any other trade name, trademark or logo of the other Party or its Affiliates.

**10.6** Binding Agreement. This Agreement, and the terms and conditions hereof, will be binding upon and will inure to the benefit of the Parties and their respective successors, heirs, administrators and permitted assigns.

**10.7** Force Majeure. Except for payment obligations under this Agreement, no Party will be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to force majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, "force majeure" is defined as causes beyond the control of the Party, including, without limitation, acts of God; Laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In the event of force majeure, Pieris or Licensee, as the case may be, will immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice will thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as such Party is so disabled, up to a maximum of [\*\*\*], after which time the Party not affected by the force majeure may terminate this Agreement. To the extent possible, each Party will use reasonable efforts to minimize the duration of any force majeure.

**10.8** Notices. Any notice or request required or permitted to be given under or in connection with this Agreement will be deemed to have been sufficiently given if in writing and

# CONFIDENTIAL TREATMENT REQUESTED

personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), email or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Pieris: Pieris Pharmaceuticals GmbH Lise-Meitner-Strasse 30 85354 Freising, Germany Attention: [\*\*\*] With a copy to: Pieris Pharmaceuticals Inc. 255 State Street, 9th Floor Boston, MA 02109 Attention: [\*\*\*]

<u>If to Servier</u>: Les Laboratoires Servier 50 rue Carnot 92284 Suresnes Cedex France Attention: [\*\*\*]

With a copy to: Attention: [\*\*\*] Les Laboratoires Servier 50 rue Carnot 92284 Suresnes Cedex France

or to such other address for such Party as it will have specified by like notice to the other Parties, provided that notices of a change of address will be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery will be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery will be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery will be deemed to be the third (3rd) day after such notice or request was deposited with the postal service. If sent by email, the date of delivery will be deemed to be the day that the Party giving notice receives electronic confirmation of sending from its email provider.

**10.9** Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances will be construed as a continuing waiver of such condition or term or of another condition or term.

#### 21

# CONFIDENTIAL TREATMENT REQUESTED

**10.10** Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

**10.11** Entire Agreement. This Agreement, including the schedules and exhibits hereto, and the Collaboration Agreement set forth all the covenants, promises, agreements, appendices, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties relating to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. To the extent of any conflict between the terms of this Agreement and its schedules and exhibits, the terms of this Agreement shall govern. In the event that there is any conflict between the Collaboration Agreement and this Agreement, then the Collaboration Agreement shall govern.

**10.12** Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party will assume, either directly or indirectly, any liability of or for the other Party. Neither Party will have the authority to bind or obligate the other Party nor will either Party represent that it has such authority.

**10.13** Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

**10.14 Construction of Agreement.** The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement will be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement will be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no

22

# CONFIDENTIAL TREATMENT REQUESTED

rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise: (a) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (b) any reference to any applicable Law herein shall be construed as referring to such applicable Law as from time to time enacted, repealed or amended; (c) any reference herein to any person shall be construed to include the person's permitted successors and assigns; (d) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (e) all references herein to Articles, Sections, or Schedules, unless otherwise specifically provided, shall be construed to refer to Articles, Sections or Schedules of this Agreement; (f) provisions that require that a Party, the Parties or any Committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, electronic mail, letter, approved minutes or otherwise (but excluding instant messaging); (g) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or" and (h) the words "will" and "shall" will have the same meaning in this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.

**10.15** Compliance with applicable Law. Each Party's obligations under this Agreement shall be subject to such Party's compliance with applicable Law applicable to its performance and its other obligations under the Agreement (including any anti-corruption, export control, environmental, hazardous substance, and data privacy and security Laws).

**10.16** No Third Party Beneficiary. Except for Section 2.2.2, nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Parties and their respective Affiliates, successors and assigns, any rights or remedies under or by reason of this Agreement.

**10.17** Counterparts. This Agreement may be signed in counterparts, each and every one of which will be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures will be treated as original signatures.

#### [Remainder of page intentionally left blank. Signature page follows.]

23

# Confidential [\*\*\*]

IN WITNESS WHEREOF, the Parties have executed this Agreement by their respective authorized representatives as of the Effective Date.

#### For Pieris Pharmaceuticals, Inc.

By: /s/ Stephen S. Yoder Name: Stephen Yoder Title: President and CEO

#### For Les Laboratoires Servier

By: <u>/s/ Christian Bazantay</u> Name: Mr. Christian BAZANTAY Title: Proxy

By: /s/ Eric Falcand Name: Mr. Eric FALCAND Title: Proxy

# For Pieris Pharmaceuticals GmbH

By: /s/ Stephen S. Yoder

Name: Stephen Yoder Title: Managing Director

# By: /s/ Emmanuel Canet

Name: Dr. Emmanuel Canet

Title: Senior Executive Vice-President Research & Development

For Institut de Recherches Internationales Servier

Exhibit A

**Platform Patents** 

[\*\*\*, 4 pages]



#### 255 State Street, 9th Floor

Boston, MA 02109

February 7, 2017

#### VIA EMAIL

Darlene Deptula-Hicks

#### **Re:** Separation Agreement

Dear Darlene:

The purpose of this letter agreement (the "Agreement") is to set forth the terms of your separation from Pieris Pharmaceuticals, Inc. ("Pieris" or the "Company"). Payment of the Separation Benefit described below is contingent on your agreement to and compliance with the terms of this Agreement. This Agreement shall become effective on the date that is the **eighth (8<sup>th</sup>) day** following your execution of it, as explained more fully in Section 6 below (the "Effective Date").

1. <u>Separation of Employment</u>. As we discussed, your employment with Pieris ended effective February 7, 2017 (the "Separation Date"). From and after the Separation Date, you shall not represent yourself or perform services as an employee of Pieris. As of the Separation Date, all salary payments from the Company shall cease and any benefits you currently have under Company-provided benefit plans, programs, or practices shall terminate, except as required by federal or state law or as otherwise set forth herein. The Company shall provide you with all wages owed through the Separation Date (including accrued but unused vacation time), and shall pay all normal and reasonable business expenses that you have incurred or shall incur in the ordinary course through the Separation Date. Receipts for any outstanding business expenses shall be submitted within ten (10) days of the date hereof. By executing this Agreement, you hereby resign from any other positions, offices or directorships you may have with the Company or any of its subsidiaries or affiliates.

2. <u>Separation Benefit</u>. In exchange for the promises and covenants contained herein, including but not limited to your release of claims, Pieris agrees to provide you with the following:

(a) <u>Severance Payments</u>. Pieris shall provide you with (i) severance pay in the form of continued payment of your gross bi-weekly Base Salary (as defined in your August 27, 2015 employment agreement with the Company, the "Employment Agreement"), less applicable

withholdings and deductions, for a period of twelve (12) months, commencing with the Company's first payroll date following the Effective Date; and (ii) a payment for the full Target Bonus Amount of your 2016 annual discretionary bonus (i.e., \$120,000), in the form of one (1) lump-sum payment, less applicable withholdings and deductions, to be paid on the Company's first payroll date following the Effective Date. You acknowledge and agree that you have not earned and are not owed any portion of the Target Bonus Amount of your 2017 annual discretionary bonus.

(b) <u>Attorneys' Fees</u>. The Company shall reimburse you for up to \$3,500 in documented attorneys' fees related to the review and negotiation of this Agreement. Such reimbursement shall be paid in accordance with applicable expense reimbursement policies; provided, however, that all reimbursements under this Section 2(b) shall be made in the 2017 calendar year.

(c) <u>Vesting of Options and Extension of Exercise Period</u>. You have been granted a non-qualified stock option to purchase 450,000 shares of the Company's common stock (the "Option") pursuant to the terms of a Stock Option Agreement dated September 1, 2015 (as amended on April 8, 2016, the "Option Agreement"), and the terms of the Company's 2016 Equity Employee, Director and Consultant Incentive Plan (the "Plan"). As of the Separation Date, 159,960 of the shares subject to the Option are vested, and 290,040 of the shares subject to the Option are unvested (the "Unvested Shares").

- i. Pieris shall accelerate the vesting of 25% of your Unvested Shares, such that your Option to purchase a total of 232,470 shares of Pieris common stock subject to the Stock Option Agreement and the Plan shall be vested (the "Vested Option") and exercisable as of the Effective Date.
- ii. The Company hereby agrees to extend the exercise period of the Vested Option to twelve (12) months following the Separation Date (the "Exercise Period") or such shorter period as set forth in Section 24 of the Plan.
- iii. You and the Company hereby agree that, in connection with any exercise of the Vested Option during the Exercise Period, you shall pay for the exercise price (but not any amounts withheld or to otherwise cover any tax obligation with respect thereto) of the Vested Option by "net exercise" as set forth in Section 10 of the Plan.
- iv. You agree that during the Exercise Period, you shall not, without the written consent of the Company, sell, assign, transfer, encumber, establish a short position or otherwise hedge or dispose of more than 50,000 shares of the Company's common stock per each rolling thirty (30) day period. Upon the completion of the Exercise Period, you will be free to transfer or dispose of the Company's common stock without limitation, except that all such transfers or dispositions shall be in compliance with applicable securities laws, including, but not limited to, the insider trading rules promulgated by the Securities and Exchange Commission.
- v. You acknowledge and agree that the unvested portion of the Option for 217,530 shares (the "Unvested Option") is hereby terminated as of the Separation Date in accordance with the terms of the Option Agreement and the Plan, and you shall have no right(s) to exercise any portion of the

Unvested Option following the Separation Date. You acknowledge and agree that the Company does not guarantee or make any representations regarding the tax consequences or tax treatment of the Vested Option. Except as modified herein, the terms and conditions of the Plan and the Stock Option Agreement are incorporated herein by reference and shall survive the signing of this Agreement.

(d) <u>Continued Healthcare</u>. By law, and regardless of whether you sign this Agreement, you shall have the right to continue your medical and dental insurance pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"). The COBRA qualifying event shall be deemed to have occurred on March 1, 2017. Upon completion of the appropriate COBRA forms and your execution of this Agreement, and subject to all the requirements of COBRA, you shall be allowed to continue participation in the Company's health and dental insurance plans at the Company's expense (except for your co-pay or your portion of premium payments, if any, which shall be paid directly by you), for the period commencing on the first day of the full calendar month following the Effective Date and (i) the date you and your covered dependents, if any, become eligible healthcare coverage under another employer's plan(s). You agree to provide the Company with written notice immediately upon securing such employment and upon becoming eligible for such benefits. Thereafter, your eligibility to continue participation in the Company's health and dental insurance plans under COBRA (including but not limited to the COBRA premium payments required for same) shall be subject to COBRA rules and provisions.

The payments and benefits provided under this Section 2 shall be referred to as the "Separation Benefit." You acknowledge and agree that the Separation Benefit is not otherwise due or owing to you under any Pieris policy or practice. For the avoidance of doubt, the above-described Separation Benefit shall be in lieu of (and not in addition to) any payments or benefits described in Section 4(b) of the Employment Agreement. You further acknowledge that except for the Separation Benefit, your final wages, any accrued but unused vacation, and any properly incurred but not yet reimbursed business expenses (each of which shall be paid or reimbursed, as the case may be, in accordance with Pieris' regular payroll practices and applicable law), you are not now and shall not in the future be entitled to any other compensation from Pieris including, without limitation, other wages, commissions, bonuses, vacation pay, holiday pay, equity, stock, stock options, paid time off, or any other form of compensation or benefit.

3. <u>Cooperation</u>. You shall cooperate fully with Pieris in connection with any matter or event relating to your employment or events that occurred during your employment, including, without limitation: (a) being available upon reasonable notice to meet with Pieris regarding matters in which you have been involved (including contract matters or audits); (b) assisting Pieris in transitioning your job duties to other Pieris personnel or contractors; (c) assisting with any audit, inspection, proceeding or other inquiry by a private or public entity; and (d) as requested by Pieris, assisting in the defense or prosecution of any claims or actions now in existence or which may be brought or threatened in the future against or on behalf of Pieris (including claims or actions against its affiliates and its and their officers and employees), including acting as a witness, providing affidavits, and preparing for, attending and participating in any legal proceeding (including depositions, consultation, discovery or trial) in connection with such claim or action. You further agree that should you be contacted (directly or indirectly) by any person or entity (for example, by any party representing an individual or entity) adverse to the Company, you shall promptly notify the President and Chief Executive Officer of the Company. You shall be reimbursed for any reasonable out-of-pocket costs and expenses approved in advance by Pieris and incurred in connection with providing such cooperation under this Section 3.

#### 4. <u>Your Additional Covenants</u>. You expressly acknowledge and agree to the following:

(a) You shall adhere to the ongoing obligations in your Employment Agreement (including, but not limited to, Section 4(a)), the Corporate Code of Conduct and Ethics, Whistleblower Policy and Insider Trading Policy between you and the Company regarding confidential information, intellectual property, and non-competition and non-solicitation (the "Agreements"), the terms of which are incorporated herein and shall survive the signing of this Agreement.

(b) You shall promptly return to the Company all Company documents (and any copies thereof), equipment and property, and you shall abide by any and all common law and statutory obligations relating to protection of the Company's trade secrets and confidential and proprietary information.

(c) In the event that you receive an order, subpoena, request, or demand for disclosure of the Company's trade secrets and/or confidential and proprietary documents and information from any court or governmental agency, or from a party to any litigation or administrative proceeding, you shall notify the Company of same as soon as reasonably possible and prior to disclosure, in order to provide the Company with the opportunity to assert its respective interests in addressing or opposing such order, subpoena, request, or demand.

(d) All information relating in any way to the negotiation of this Agreement, including the terms and amount of financial consideration provided for in this Agreement, shall be held confidential by you and shall not be publicized or disclosed to any person (other than an immediate family member, legal counsel or financial advisor, provided that any such whom disclosure is made agrees to be bound by these confidentiality obligations), to any government agency (except as mandated by state or federal law), or to any business entity.

(c) You shall not make any statements that are disparaging about the Company or its officers, directors, managers or employees, including, but not limited to, any statements that disparage any program, service, finances, financial condition, capability or any other aspect of the business of the Company, and you shall not engage in any conduct which is intended to harm professionally or personally the reputation of the Company or its officers, directors, managers or employees. The Company agrees that its executive management team and members of its board of directors will not make any statements that are disparaging about you and will not engage in any conduct which is intended to harm professionally or personally your reputation. In response to inquiries from third parties concerning your employment and/or departure, the Company's response will be consistent with the substance of the press release issued by the Company in connection with your departure.

(f) A breach of any provision of this Section 4 shall constitute a material breach of this Agreement and, in addition to any other legal or equitable remedy available to the Company, shall entitle the Company to recover the Separation Benefit provided to you under this Agreement.

#### 5. Your Release of Claims.

(a) <u>Release</u>. You hereby agree that by signing this Agreement and accepting the Separation Pay, Separation Benefits and other good and valuable consideration provided for in this Agreement, you are waiving and releasing your right to assert any form of legal claim against the Company<sup>1/</sup> whatsoever for any alleged action, inaction or circumstance existing or arising from the beginning of time through the Effective Date. Your waiver and release herein is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "Claims") against the Company seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against the Company, for any alleged action, inaction or circumstance existing or arising through the Effective Date. Without limiting the foregoing general waiver and release, you specifically waive and release the Company from any Claim arising from or related to your employment relationship with the Company or the termination thereof, including, without limitation:

(i) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to employment, discrimination, fair employment practices, or other terms and conditions of employment, including but not limited to the Age Discrimination in Employment Act and Older Workers Benefit Protection Act (29 U.S.C. § 621 et seq.), the Civil Rights Acts of 1866 and 1871 and Title VII of the Civil Rights Act of 1964 and the Civil Rights Act of 1991 (42 U.S.C. § 2000e et seq.), the Equal Pay Act (29 U.S.C. § 201 et seq.), the Americans With Disabilities Act (42 U.S.C. § 12101 et seq.), the Genetic Information Non-Discrimination Act (42 U.S.C. § 2000ff et seq.), the Massachusetts Fair Employment Practices Statute (M.G.L. c. 151B § 1 et seq.), the Massachusetts Equal Rights Act (M.G.L. c. 214 § 11), the Massachusetts Privacy Statute (M.G.L. c. 214 § 12), the Massachusetts Sexual Harassment Statute (M.G.L. c. 214 § 1C), and any similar Massachusetts or other state or federal statute.

(ii) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to leaves of absence, layoffs or reductions-in-force, wages, hours, or other terms and conditions of employment, including but not limited to the National Labor Relations Act (29 U.S.C. § 151 et seq.), the Family and Medical Leave Act (29 U.S.C. §2601 et seq.), the Employee Retirement Income Security Act of 1974 (29 U.S.C. § 1000 et seq.), COBRA (29 U.S.C. § 1161 et seq.), the Worker Adjustment and Retraining Notification Act (29 U.S.C. § 2101 et seq.), the Uniformed Services Employment and Reemployment Rights Act of 1994 (38 U.S.C. § 4301 et seq.), the Massachusetts Wage Act (M.G.L. c. 149 § 148 et. seq.), the Massachusetts Minimum Fair Wages Act (M.G.L. c. 149 § 105A), and any similar Massachusetts or other state or federal statute. *Please note that this section specifically includes a waiver and release of Claims that you have or may have regarding payments or amounts covered by the Massachusetts Wage Act or the Massachusetts Minimum Fair Wages Act (including, for instance, hourly wages, salary, overtime, minimum wages, commissions, vacation pay, holiday pay, sick leave pay, dismissal pay, bonus pay or severance pay), as well as Claims for retaliation under the Massachusetts Wage Act or the Massachusetts Minimum Fair Wages Act.* 

<sup>&</sup>lt;sup>1/</sup> For the purposes of this Section 5, the parties agree that the term "Company" shall include Pieris Pharmaceuticals, Inc., its divisions, affiliates, parents and subsidiaries, and any of its and their respective officers, directors, shareholders, employees, consultants, contractors, attorneys, agents and assigns.

(iii) Claims under any state or federal common law theory, including, without limitation, wrongful discharge, breach of express or implied contract, promissory estoppel, unjust enrichment, breach of a covenant of good faith and fair dealing, violation of public policy, defamation, interference with contractual relations, intentional or negligent infliction of emotional distress, invasion of privacy, misrepresentation, deceit, fraud or negligence or any claim to attorneys' fees under any applicable statute or common law theory of recovery.

(iv) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to violation of public policy or any other form of retaliation or wrongful termination, under any federal or any similar Massachusetts or other state or federal statute.

(v) Claims under any Company employment, compensation, benefit, stock option, incentive compensation, bonus, restricted stock, and/or equity plan, program, policy, practice or agreement, including, without limitation the Employment Agreement and the Option Agreement.

(vi) Any other Claim arising under any other state or federal law.

You explicitly acknowledge that because you are over forty (40) years of age, you have specific rights under the ADEA, which prohibits discrimination on the basis of age, and that the releases set forth in this Section 5 are intended to release any right that you may have to file a claim against the Company alleging discrimination on the basis of age.

(b) <u>Release Exclusions</u>. Notwithstanding the foregoing, this Section 5 <u>does not</u>: (i) release the Company from any obligation expressly set forth in this Agreement or from any obligation, including without limitation obligations under the Workers Compensation laws, which as a matter of law cannot be released; (ii) release any right to indemnification under the Company's Bylaws, Articles of Incorporation, and/or directors' and officers' liability insurance policies as of the Separation Date, subject to the terms and conditions of same (iii) prohibit you from filing a charge with the Equal Employment Opportunity Commission ("EEOC"), the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, or any other federal, state or local governmental agency or commission (a "Government Agency"); (iv) prohibit you from participating in an investigation or proceeding by a Government Agency, communicating with a Government Agency, or providing information or documents to a Government Agency; or (v) prohibit you from challenging or seeking a determination in good faith of the validity of this release or waiver under applicable state or federal law, or impose any condition precedent, penalty, or costs for doing so unless specifically authorized by state or federal law. Your waiver and release, however, are intended to be a complete bar to any recovery or personal benefit by or to you with respect to any claim whatsoever, including those raised through a charge with the EEOC or comparable federal, state or local governmental agency, except those which, as a matter of law, cannot be released.

(c) <u>Acknowledgment</u>. You acknowledge and agree that, but for providing this waiver and release, you would not be receiving the Separation Benefit being provided to you under the terms of this Agreement. You further agree that should you breach this Section 5, the Company, in addition to any other legal or equitable remedy available to the Company, shall be entitled to recover any the cost of the Separation Benefit previously provided to you pursuant to Section 2 hereof.

6. <u>ADEA/OWBPA Review and Revocation Period</u>. You and Pieris acknowledge that you are over the age of 40 and that you, therefore, have specific rights under the Age Discrimination in Employment Act ("ADEA") and the Older Workers Benefit Protection Act (the "OWBPA"), which prohibit discrimination on the basis of age. It is Pieris' desire and intent to make certain that you fully understand the provisions and effects of this Agreement. To that end, you have been encouraged and given the opportunity to consult with legal counsel for the purpose of reviewing the terms of this Agreement. Consistent with the provisions of the ADEA and OWBPA, Pieris also is providing you with twenty one (21) days in which to consider and accept the terms of this Agreement by signing below and returning it to Stephen S. Yoder, President and Chief Executive Officer, Pieris Pharmaceuticals, Inc., 255 State Street, 9th Floor, Boston, MA 02129. You agree that any modifications, material or otherwise, made to this Agreement do not and shall not restart or affect in any manner whatsoever, the original 21-day Review Period. You may rescind your assent to this Agreement if, within seven (7) days after you sign this Agreement, you deliver by hand or send by mail (certified, return receipt and postmarked within such 7-day period) a notice of rescission at the above-referenced address.

7. <u>Opportunity to Disclose</u>. You acknowledge that you have been provided the opportunity to advise the Company as to any concerns regarding its financial statements, SEC filings and other public disclosures or any other matters, and have confirmed to the Company that you have no such concerns.

8. <u>Taxes and Withholdings</u>. The Separation Benefit provided under this Agreement shall be reduced by all applicable federal, state, local and other deductions, taxes, and withholdings. Pieris does not guarantee the tax treatment or tax consequences associated with any payment or benefit under this Agreement, including but not limited to consequences related to Section 409A of the Code.

9. <u>Modification; Waiver; Severability</u>. No variations or modifications hereof shall be deemed valid unless reduced to writing and signed by the parties hereto. The failure of Pieris to seek enforcement of any provision of this Agreement in any instance or for any period of time shall not be construed as a waiver of such provision or of Pieris' right to seek enforcement of such provision in the future. The provisions of this Agreement are severable, and if for any reason any part hereof shall be found to be unenforceable, the remaining provisions shall be enforced in full.

10. <u>Choice of Law and Venue; Jury Waiver</u>. This Agreement shall be deemed to have been made in Massachusetts, shall take effect as an instrument under seal within Massachusetts, and shall be governed by and construed in accordance with the laws of Massachusetts, without giving effect to conflict of law principles. You agree that any action, demand, claim or counterclaim relating to the terms and provisions of this Agreement, or to its breach, shall be commenced in Massachusetts in a court of competent jurisdiction, and you further acknowledge that venue for such actions shall lie exclusively in Massachusetts and that material witnesses and documents would be located in Massachusetts.

11. <u>Entire Agreement</u>. You acknowledge and agree that this Agreement, along with the specific agreements that are expressly incorporated herein by reference and stated as surviving the signing of this Agreement, supersede any and all prior or contemporaneous oral and written agreements between you and Pieris, and set forth the entire agreement between you and Pieris.

12. <u>Knowing and Voluntary Agreement</u>. By executing this Agreement, you are acknowledging that you have been afforded sufficient time to understand the terms and effects of this Agreement, that your agreements and obligations hereunder are made voluntarily, knowingly and without duress, and that neither Pieris nor its agents or representatives have made any representations inconsistent with the provisions of this Agreement.

# [REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

This Agreement may be signed on one or more copies, each of which when signed shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. If the foregoing correctly sets forth our understanding, please sign, date and return the enclosed copy of this Agreement to me. If Pieris does not receive your acceptance within **twenty-one (21) days**, the Agreement shall terminate and be of no further force or effect.

Sincerely,

# PIERIS PHARMACEUTICALS, INC.

By: /s/ Stephen S. Yoder

Stephen S. Yoder President and Chief Executive Officer

Dated: February 7, 2017

Agreed and Acknowledged:

/s/ Darlene Deptula-Hicks Darlene Deptula-Hicks

Dated: February 7, 2017

# **EMPLOYMENT AGREEMENT**

This Employment Agreement (the "<u>Agreement</u>") is made and entered into by and between **Claude Knopf** ("<u>Executive</u>") and **Pieris Pharmaceuticals, Inc.**, a Nevada corporation (the "<u>Company</u>") (together referred to herein as the "<u>Parties</u>"), effective as of November 11, 2016 (the "<u>Effective Date</u>").

## RECITALS

WHEREAS, the Company desires to employ Executive as Sr. Vice President and Chief Business Officer of the Company and Executive desires to accept such employment, subject to the terms and conditions contained in this Agreement,

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

### 1. Employment.

(a) <u>Term of Agreement</u>. This Agreement shall become effective on the Effective Date and shall continue unless terminated in accordance with the terms and conditions contained in Sections 3 and 4 of this Agreement (the "<u>Term</u>"). Executive's employment shall begin on November 14, 2016, unless otherwise agreed to in writing by the Parties (the "<u>Start Date</u>"), and at all times shall be "at-will".

(b) <u>Position and Duties</u>. Subject to the terms and conditions of this Agreement, the Company agrees to employ Executive during the Term as Sr. Vice President and Chief Business Officer of the Company and as such he shall report to the Chief Executive Officer of the Company. Executive shall perform such duties and bear the responsibilities as are customarily associated with this position as well as such other duties as shall be specified and designated from time to time by the Company's Chief Executive Officer, his designee, and/or the Company's board of directors (the "<u>Board</u>").

(c) <u>Location</u>. Executive shall perform services for the Company at the Company's offices located in Boston, MA; *provided*, *however*, that the Company may from time to time require Executive to travel to other locations in connection with the Company's business on a reasonable basis. For purposes of clarity, Executive is not required to move his office from the Boston Location.

## (d) Exclusivity.

(i) During the Term, Executive shall devote all of Executive's business time and energies to the business and affairs of Company and its Affiliates and to the faithful and diligent performance of the duties and responsibilities described herein. During the Term, Executive shall not (A) accept any other employment or consultancy or (B) serve on the board of directors or similar body of any entity, unless such position is approved by the Chief Executive Officer as set forth in subsection (d)(ii) below (which such

approval shall continue until such time as the Company provides notice to Executive that, in its reasonable judgment, such position is with a Competing Entity, interferes with Executive's duties to the Company or places Executive in a Competing Position with, or otherwise conflicts with, the interests of the Company, at which time the Company and Executive will discuss such conflict and the parties will use reasonable efforts to reach agreement on its resolution); provided that Executive may engage in civic and not-for-profit activities, so long as such activities, in the aggregate, do not conflict with the interests of the Company or materially interfere with the performance of Executive's duties to the Company and do not otherwise conflict with subsection (d)(ii) below.

(ii) During Executive's employment by the Company, Executive agrees not to acquire, assume or participate in, directly or indirectly, any financial position, investment or interest known by Executive to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise or in any Competing Entity, directly or indirectly; provided, however, Executive may accept equity compensation related to the positions or business activities engaged in which have been approved by the Company pursuant to subsection (d)(i) above. Ownership by Executive, as a passive investment, of less than two percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed on a national securities exchange or publicly traded on a national securities exchange or in the over-the-counter market shall not constitute breach of this Section 1(d).

(iii) The Executive hereby represents to the Company that: (i) the execution and delivery of this Agreement by the Executive and the Company and the performance by the Executive of the Executive's duties hereunder do not and shall not constitute a breach of, conflict with, or otherwise contravene or cause a default under, the terms of any other agreement or policy to which the Executive is a party or otherwise bound or any judgment, order or decree to which the Executive is subject; (ii) in entering into this Agreement and carrying out Executive's duties under this Agreement, Executive will not disclose to the Company any trade secret, confidential or proprietary information belonging to any other Person, including any previous employer, and that Executive shall not bring with Executive any such information to the Company; (iii) the Executive is not bound by any agreement with any previous employer or other party to refrain from competing with the business of, which would be violated by your employment with the Company; and (iv) all facts Executive has presented or will present to the Company in connection with entering into this Agreement and an employment relationship with the Company are accurate and true, and this includes all oral and written statements Executive has made to the Company (including, but not limited to, those pertaining to any agreements Executive previously entered into containing restrictive covenants, Executive's prior work experience, and Executive's prior exposure to trade secrets, confidential and proprietary information), and Executive understands that the Company will rely upon the accuracy and truth of the representations and warranties of the Executive set forth herein and the Executive consents to such reliance.

- 2 -

### 2. Compensation and Related Matters.

(a) <u>Base Salary</u>. Executive's annual base salary ("<u>Base Salary</u>") will be \$370,000 in U.S. Dollars, less payroll deductions and all required withholdings, payable in accordance with the Company's normal payroll practices in effect from time to time. The Board or a committee of the Board shall review Executive's Base Salary at least annually to determine if adjustments upward to Executive's Base Salary, if any, will be made solely at the discretion of the Board or a committee of the Board.

(b) <u>Bonus</u>. Executive shall also be eligible for an annual discretionary bonus of up to 40% of Executive's then-Base Salary (the "<u>Target Bonus Amount</u>") as determined by the Board or a committee of the Board in its sole discretion, based upon the Board's or a committee of the Board's evaluation (in its sole discretion) of the achievement of specific individual and/or Company-wide performance goals as chosen and determined by the Board or a committee of the Board in its sole discretion. The annual discretionary bonus, if any, shall be payable, less authorized deductions and required withholdings, no later than March 15<sup>th</sup> of the calendar year immediately following the calendar year in which it was earned. The Target Bonus Amount of any annual discretionary bonus for which Executive is eligible shall be reviewed by the Board or a committee of the Board from time to time. Notwithstanding the above, the Company, subject to the sole discretion of the CEO and the Board, may increase the Target Bonus Amount.

(c) Equity Awards. Subject to approval of the Board or an appropriate committee thereof, Company shall grant Executive on the Start Date or as soon thereafter as practicable, a nonqualified stock option to purchase 500,000 shares of common stock of the Company (the "<u>Option</u>"). Twenty-five percent (25%) of the Option shall vest on the first anniversary of the Start Date (the "<u>Initial Vesting Date</u>"), with the remaining seventy-five percent (75%) of the Option to vest over the next three years in quarterly installments after the Initial Vesting Date, subject in each case to Executive's continued employment in Good Standing. The option shall be evidenced in writing by a stock option agreement, and subject to terms and conditions substantially similar to the Plan and the Company's standard form of stock option agreement. The stock option agreement shall expire ten (10) years from the date of grant except as otherwise provided herein or in the stock option agreement.

(d) <u>Benefits</u>. During the Term, the Company, shall provide Executive with coverage under all employee benefit programs, plans and practices as are in effect from time to time and which the Company, makes available from time to time to its senior executive officers, with at least the same opportunity to participate as the other senior executive officers of the Company, including, without limitation, if applicable, retirement, pension, medical, dental, hospitalization, life insurance, short and long term disability, accidental death and dismemberment and travel accident coverage.

- 3 -

(e) <u>Vacation and Fringe Benefits</u>. Executive shall be entitled to four (4) weeks paid vacation in each calendar year (pro-rated as necessary for partial calendar years during the Term). Executive may take his vacation at such times consistent with the vacation policies as are in effect from time to time with respect to senior executive officers. Executive shall be entitled to the perquisites and fringe benefits which the Company makes available from time to time to its senior executive officers, commensurate with Executive's position with the Company.

(f) <u>Business Expenses</u>. During the Term, the Company shall reimburse Executive for all reasonable business expenses incurred in the conduct of Executive's duties hereunder in accordance with the applicable expense reimbursement policies.

## 3. Termination.

(a) <u>At-Will Employment</u>. The Company and Executive acknowledge that Executive's employment is and shall continue to be "at-will," as defined under applicable law. This means that it is not for any specified period of time and can be terminated by any of the parties hereto at any time, with or without advance notice (other than as stated herein), and for any or no particular reason or cause. It also means that Executive's job duties, title and responsibility, compensation and benefits, as well as the personnel policies and procedures in effect, may be changed with prospective effect, with or without notice, at any time in the sole discretion of the Company. This "at-will" nature of Executive's employment shall remain unchanged during Executive's tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized member of the Board. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, awards or compensation other than as provided by this Agreement.

(b) <u>Deemed Resignation</u>. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its Affiliates, and, at the Company's request, Executive shall execute such documents as are necessary or desirable to effectuate such resignations.

### 4. Obligations During and Subsequent to Executive's Employment.

## (a) Executive's Obligations.

(i) <u>Notice Period</u>. Anything in this Agreement notwithstanding, Executive may voluntarily terminate his employment hereunder upon not less than thirty (30) days prior written notice of Executive delivered to the Company, or upon such shorter notice as Executive and the Company shall agree.

(ii) <u>Confidentiality</u>. Executive shall not during the Term and thereafter, without the prior written consent of the Company, knowingly (i) divulge, disclose or make accessible any Confidential Information (as defined below) to any other person, firm, partnership, corporation or other entity or (ii) use any Confidential Information for his own purposes or for the benefit of any other person, firm, partnership, corporation or other entity (other than the Company), except (x) during the Term, in the business of and for the benefit of the Company or (y) when required to do so by a court of competent

- 4 -

jurisdiction, by any governmental agency having supervisory authority over the business of the Company, or by any administrative body or legislative body (including a committee thereof) with jurisdiction to order Executive to divulge, disclose or make accessible such Confidential Information or by state, federal, foreign or local law, rule or regulation; provided that, in the event that Executive is so required to disclose Confidential Information, Executive shall, prior to making any such disclosure, provide the Company with prompt written notice of such requirement so that the Company may seek an appropriate protective order. For purposes of this Agreement, "Confidential Information" shall mean all confidential Company data, analyses, reports, interpretations, forecasts, documents and information concerning the affairs of the Company and its Affiliates, including, without limitation, confidential financial data, strategic business plans, computer programs and documentation, product development data (or other proprietary product data), customer lists and customer information, discoveries, practices, policies, processes, methods, marketing plans, prospects, opportunities and other proprietary information and trade secrets in whatever form, tangible or intangible; provided that Confidential Information shall not include (x) information that has become generally available to the public other than as a result of disclosure by Executive in a manner violative of this Section 4, or (y) information that is rightly received by Executive without restriction on disclosure from a third party legally entitled to possess and disclose such information without restriction (other than information that Executive may learn or has learned by reason of his association with any Affiliate). Upon conclusion of the Term or at any point prior on request of the Company, Executive shall immediately return to the Company all Confidential Information, including copies, reproductions and summaries thereof, in his possession and shall erase all such Confidential Information from all media in his possession, and, if the Company so requests, shall certify in writing that he has done so. All Confidential Information is and shall remain the property of the Company and its Affiliates.

(iii) <u>Trade Secrets</u>. For purposes of this Agreement, the term "trade secrets," shall be given its broadest possible interpretation under applicable law and shall mean all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing that (i) the Company has taken reasonable measures to keep secret, and that (ii) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

(iv) <u>Non-Competition</u>. During the Term and twelve (12) months thereafter, Executive agrees that, without the prior written consent of the Board (which the Board may grant or withhold in its discretion): he shall not serve in or otherwise occupy a Competing Position at, or have any financial interest in, any Competing Entity, except that it will not be deemed a breach of this Section 4(a)(iii) if Executive is an investor or stockholder of not more than two (2%) percent of the equity securities of any entity.

- 5 -

(v) <u>Non-Solicitation</u>. During the Term and for twelve (12) months thereafter, Executive agrees that, without the prior written consent of the Board he shall not, on his own behalf or on behalf of any person or entity, directly or indirectly, (a) solicit for employment any employee who has been employed by the Company or any Affiliate at any time during the twelve (12) months immediately preceding such solicitation or offer or (b) solicit for the business of or provide services to any client, customer, or vendor of the Company or any Affiliate for which he or any subordinate provided services during the Term.

(vi) Intellectual Property. All Intellectual Property (as defined below) and Technology (as defined below) created, developed, obtained or conceived of by Executive during the Term, and all business opportunities presented to Executive during the Term shall be owned by and belong exclusively to the Company, provided that they directly relate to the business of the Company, as of the date of such creation, development, obtaining or conception, and Executive shall (i) promptly disclose to the Company any such Intellectual Property or Technology or any viable business opportunity presented by a third party to Executive during the Term and which the Company has not rejected and (ii) execute and deliver to the Company, without additional compensation, such instruments (such as assignments of any Intellectual Property to the Company) as the Company may require from time to time to evidence its ownership of any such Intellectual Property or Technology or business opportunity. For purposes of this Agreement, (x) the term "Intellectual Property" shall mean and include any and all trademarks, trade names, service marks, service names, patents, copyrights and applications therefor and (y) the term "Technology" shall mean and include any and. all trade secrets, proprietary information, inventions, discoveries, know-how, formulae, processes and procedures.

(vii) <u>Non-disparagement</u>. During the Term and at all times thereafter, unless as required by law, including through a valid subpoena, Executive shall not make, or cause to be made, any statement or communicate any information (whether oral or written) that disparages or reflects negatively on the Company or its Affiliates, officers, directors, board members, investors, shareholders, agents or employees.

(viii) <u>Response to Legal Process</u>. During the Term and twelve (12) months thereafter, Executive may respond to a lawful and valid subpoena or other legal process but shall give the Company the earliest possible notice thereof, and shall, as much in advance of the return date as possible, make available to the Company and its counsel the documents and other information sought, and shall assist such counsel with his or her reasonable requests in resisting or otherwise responding to such process.

- 6 -

(ix) Notice Pursuant to Defend Trade Secrets Act. Notwithstanding any provision of this Agreement prohibiting the disclosure of trade secrets or other Confidential Information, Executive understands that Executive may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney representing Executive, and (B) solely for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, if Executive files a lawsuit or other court proceeding against the Company for retaliating against Executive for reporting a suspected violation of law, Executive may disclose the trade secret to the attorney representing Executive and use the trade secret in the court proceeding, so long as Executive files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

(x) <u>Survival of Provisions</u>. The provisions of this Section 4(a) shall survive the termination or expiration of the applicable Executive's employment with the Company and shall be fully enforceable thereafter. If it is determined by a court of competent jurisdiction that any restriction in this Section 4(a) is excessive in duration or scope or is unreasonable or unenforceable under the laws of that jurisdiction, it is the intention of the parties that such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the law of that jurisdiction.

(xi) <u>Injunctive Relief.</u> Executive and the Company agree that the restrictions contained in Sections 4(a) hereof are a reasonable and necessary protection of the immediate interests on the Company, that any violation of these restrictions would cause substantial injury to the Company and that the Company would not have entered into this Agreement without receiving the additional consideration offered by Executive in binding himself to these restrictions. In the event of the breach or threatened breach by Executive of any of such restrictions, the Company shall be entitled to apply to any court of competent jurisdiction for an injunction restraining Executive for such breach or threatened breach, including, but not limited to, a civil seizure order under the Defend Trade Secrets Act; provided that the right of the Company to apply for an injunction shall not be construed as prohibiting the Company from pursuing any other available remedies for such breach or threatened breach. In the event that, notwithstanding the foregoing, a restriction, or any portion thereof, contained in Section 4(a) is deemed to be unreasonable by a court of competent jurisdiction, whether due to the passage of time, change of circumstances or otherwise, Executive and the Company agree that such restriction, or portion thereof, shall be modified in order to make it reasonable and shall be enforced accordingly.

- 7 -

### (b) Company's Obligations.

(i) <u>Payments of Accrued Obligations upon Termination of Employment</u>. Upon a termination of Executive's employment for any reason, Executive (or Executive's estate or legal representative, as applicable) shall be entitled to receive, within ten (10) days after the date Executive terminates employment with the Company (or such earlier date as may be required by applicable law): (i) any portion of Executive's annual base salary earned through Executive's termination date not theretofore paid, (ii) any expenses owed to Executive under Section 2(f) above, (iii) any accrued but unused vacation pay owed to Executive pursuant to Section 2(e) above, and (iv) any amount arising from Executive's participation in, or benefits under, any employee benefit plans, programs or arrangements under Section 2(d) above, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements.

(ii) <u>Separation Benefits upon a Covered Termination Other Than During a Change in Control Period</u>. If Executive experiences a Covered Termination at any time other than during a Change in Control Period, and if Executive executes and does not revoke during any applicable revocation period a general release of all claims against the Company and its Affiliates in a form acceptable to the Company (a "<u>Release of Claims</u>") within the sixty (60) day period immediately following Executive's Separation from Service and in compliance with applicable law, following such Covered Termination, then in addition to any accrued obligations payable under Section 4(b)(i) above, the Company shall provide Executive with the following:

(A) <u>Separation Pay</u>. Twelve (12) months (the "<u>Separation Pay Period</u>") of Executive's Base Salary in effect as of Executive's termination date (the "<u>Separation Pay</u>"). Such amount will be subject to applicable withholdings and payable in twelve equal installments (the "<u>Separation Pay Installments</u>") on the first regular payroll date following the date the Release of Claims becomes effective and irrevocable or if the payment is subject to Section 409A, the date set forth in Section 10(a) hereof.

(B) <u>Bonus</u>. Executive's Target Bonus Amount in effect as of the termination date, pro-rated based on the total number of days elapsed in the calendar year as of the termination date, but only if, as of the date of Executive's termination of employment, the Company and Executive were "on target" to achieve all applicable performance goals for such discretionary annual bonus as determined by the Board or a committee of the Board in their reasonable discretion; plus any annual discretionary bonus that the Company awarded to Executive in the year prior to the termination but which Company still had not paid to Executive as of the termination date. Such amount will be subject to applicable withholdings and payable in a single lump sum cash payment on the first regular payroll date following the date the Release of Claims becomes effective and irrevocable or if the payment is subject to Section 409A, the date set forth in Section 10(a) hereof.

- 8 -

(C) <u>Equity Awards</u>. Each outstanding equity award, including, without limitation, each stock option held by Executive, shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions shall immediately lapse with respect to seventy-five percent (75%) of the then unvested equity awards as of the date the Release of Claims becomes effective and irrevocable; provided, however, that if the equity award is subject to Section 409A and payable upon vesting, payment of such equity award shall be made on the date set forth in Section 10(a) hereof.

(D) <u>Continued Healthcare</u>. The Company shall notify Executive of any right to continue group health plan coverage sponsored by the Company or an Affiliate immediately prior to Executive's date of termination pursuant to the provisions of applicable law including, but not limited to, the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("<u>COBRA</u>"). If Executive elects to receive such continued healthcare coverage, the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents, less the amount of Executive's monthly premium contributions for such coverage prior to termination, for the period commencing on the first day of the first full calendar month following the date the Release of Claims becomes effective and irrevocable through the earlier of (i) the last day of the twelve (12) full calendar months following the date the Release of Claims becomes effective and irrevocable and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Executive shall notify the Company immediately if Executive becomes covered by a group health plan of a subsequent employer. After the Company ceases to pay premiums pursuant to this subsection, Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA or other applicable law.

(iii) <u>Separation Benefits upon a Covered Termination During a Change in Control Period</u>. If Executive experiences a Covered Termination during a Change in Control Period, and if Executive executes and does not revoke during any applicable revocation period a Release of Claims within a reasonable period of time specified by the Company, following such Covered Termination, then in addition to any accrued obligations payable under Section 4(b)(i) above, the Company shall provide Executive with the following:

(A) <u>Separation Pay</u>. Twelve (12) months of Separation Pay. Such amount will be subject to applicable withholdings and payable in twelve equal installments on the first regular payroll date following the date the Release of Claims becomes effective and irrevocable or if the payment is subject to Section 409A, the date set forth in Section 10(a) hereof.

- 9 -

(B) <u>Bonus</u>. Executive's Target Bonus Amount in effect as of the termination date; plus any annual discretionary bonus that the Company awarded to Executive in the year prior to the termination but which Company still had not paid to Executive as of the termination date. Such amount will be subject to applicable withholdings and payable in a single lump sum cash payment on the first regular payroll date following the date the Release of Claims becomes effective and irrevocable or if the payment is subject to Section 409A, the date set forth in Section 10(a) hereof.

(C) <u>Equity Awards</u>. Each outstanding equity award, including, without limitation, each stock option held by Executive shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions shall immediately lapse with respect to seventy-five percent (75%) of the then unvested equity awards as of the date the Release of Claims becomes effective and irrevocable; provided, however, that if the equity award is subject to Section 409A and payable upon vesting, payment of such equity award shall be made on the date set forth in Section 10(a) hereof.

(D) <u>Continued Healthcare</u>. The Company shall notify Executive of any right to continue group health plan coverage sponsored by the Company or an Affiliate immediately prior to Executive's date of termination pursuant to the provisions of applicable law including, but not limited to, the provisions of COBRA. If Executive elects to receive such continued healthcare coverage, the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents, less the amount of Executive's monthly premium contributions for such coverage prior to termination, for the period commencing on the first day of the first full calendar month following the date the Release of Claims becomes effective and irrevocable through the earlier of (i) the last day of the twelve (12) full calendar months following the date the Release of Claims becomes effective and irrevocable and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Executive shall notify the Company immediately if Executive becomes covered by a group health plan of a subsequent employer. After the Company ceases to pay premiums pursuant to this subsection, Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA or other applicable law.

(iv) <u>No Other Severance</u>. The provisions of this Section 4(b) shall supersede in their entirety any severance payment or other arrangement provided by the Company, including, without limitation, any severance plan of the Company.

(c) <u>Release of Claims.</u> The Company shall provide a form Release of Claims to Executive within five (5) business days of Executive's termination date.

- 10 -

#### (d) No Requirement to Mitigate; Separation Pay Offset; Survival.

(i) Executive shall not be required to mitigate the amount of any payment provided for under this Agreement by seeking other employment or in any other manner.

(ii) In the case of Covered Termination Other Than During a Change in Control Period under Section 4(b)(ii)(A), if Executive accepts a Bona Fide Offer of Employment (as defined below) from another Person during the Separation Pay Period, Executive shall no longer be entitled to each of the twelve (12) Separation Pay Installments under Section 4(b)(ii)(A). Instead, in addition to the Separation Pay Installments Executive previously paid to Executive:

(A) If Executive accepts a Bona Fide Offer of Employment on or before the six (6) month anniversary of the Separation Pay Period, then Executive shall be entitled to an amount equal to six (6) months, less the number of Separation Pay Installments previously paid to Executive; or

(B) If Executive accepts a Bona Fide Offer of Employment after the six (6) month anniversary of the Separation Pay Period, then Executive shall not be entitled to receive any further Separation Pay Installments.

For the sake of clarity, under no circumstances shall Executive receive less than six (6) months of Separation Pay in the case of a Covered Termination Other Than During a Change in Control Period.

(iii) Executive shall notify the Company in writing of Executive's acceptance of a Bona Fide Offer of Employment within two (2) business days of such offer. Executive further agrees that the compensation paid in connection with any such Bona Find Offer of Employment will be negotiated in good faith and as the result of arm's-length bargaining and not with the effect of diminishing the Company's right to reduce the Separation Pay under this Agreement.

(iv) Notwithstanding anything to the contrary in this Agreement, the termination of Executive's employment shall not impair the rights or obligations of any party.

- 11 -

5. Limitation on Payments. Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Executive would receive pursuant to this Agreement or otherwise ("Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Payment are paid to Executive, which of the following alternative forms of payment would maximize Executive's after-tax proceeds: (i) payment in full of the entire amount of the Payment (a "Full Payment"), or (ii) payment of only a part of the Payment so that Executive receives that largest Payment possible without being subject to the Excise Tax (a "Reduced Payment"), whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax (all computed at the highest marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes), results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment, notwithstanding that all or some portion the Payment may be subject to the Excise Tax.

(a) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 5. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, group or entity effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(b) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive at such time as requested by the Company or Executive. If the independent registered public accounting firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Payment, it shall furnish the Company and Executive with an opinion reasonably acceptable to Executive that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

# 6. Successors.

(a) <u>Company's Successors</u>. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this Section 6(a) or which becomes bound by the terms of this Agreement by operation of law.

- 12 -

(b) <u>Executive's Successors</u>. The terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

7. <u>Notices</u>. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or one day following mailing via Federal Express or similar overnight courier service. In the case of Executive, mailed notices shall be addressed to Executive at Executive's home address that the Company has on file for Executive. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of the Chairman of the Compensation Committee of the Company.

8. Dispute Resolution. To ensure the timely and economical resolution of disputes that arise in connection with this Agreement, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance or interpretation of this Agreement, Executive's employment, or the termination of Executive's employment, shall be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in Boston, Massachusetts, conducted by Judicial Arbitration and Mediation Services, Inc. ("JAMS") under the applicable JAMS employment rules. By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS' arbitration fees in excess of the amount of court fees that would be required if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by Court action instead of arbitration.

### 9. Miscellaneous Provisions.

(a) <u>Withholdings and Offsets</u>. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on an opinion of counsel if any questions as to the amount or requirement of withholding shall arise.

- 13 -

(b) <u>Waiver</u>. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) <u>Whole Agreement</u>. This Agreement represents the entire understanding of the parties hereto with respect to the subject matter hereof and supersede all prior arrangements and understandings regarding same, including, without limitation, any severance plan of the Company.

(d) <u>Choice of Law</u>. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

(e) <u>Severability</u>. The finding by a court of competent jurisdiction of the unenforceability, invalidity or illegality of any provision of this Agreement shall not render any other provision of this Agreement unenforceable, invalid or illegal. Such court shall have the authority to modify or replace the invalid or unenforceable term or provision with a valid and enforceable term or provision which most accurately represents the intention of the parties hereto with respect to the invalid or unenforceable term or provision.

(f) <u>Interpretation; Construction</u>. The headings set forth in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement. This Agreement has been drafted by legal counsel representing the Company, but Executive has been encouraged to consult with, and has consulted with, Executive's own independent counsel and tax advisors with respect to the terms of this Agreement. The parties hereto acknowledge that each party hereto and its counsel has reviewed and revised, or had an opportunity to review and revise, this Agreement, and any rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement.

(g) <u>Representations</u>; <u>Warranties</u>. Executive represents and warrants that Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that Executive's execution and performance of this Agreement will not violate or breach any other agreements between Executive and any other person or entity and that Executive has not engaged in any act or omission that could be reasonably expected to result in or lead to an event constituting "Cause" for purposes of this Agreement.

(h) <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

- 14 -

10. Section 409A. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Code and the Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date, ("Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. If the Company determines that any provision of this Agreement would cause Executive to incur any additional tax or interest under Section 409A (with specificity as to the reason therefor), the Company and Executive shall take commercially reasonable efforts to reform such provision to try to comply with or be exempt from Section 409A, *provided* that any such modifications shall not increase the cost or liability to the Company. To the extent that any provision hereof is modified in order to comply with or be exempt from Section 409A, such modification shall be made in good faith and shall, to the maximum extent reasonably possible, maintain the original intent and economic benefit to Executive and the Company of the applicable provision without violating the provisions of Section 409A.

(a) Separation from Service. Notwithstanding any provision to the contrary in this Agreement, no amount that is subject to Section 409A of the Code shall be payable pursuant to Section 4 unless Executive's termination of employment constitutes a "separation from service" with the Company within the meaning of Section 409A ("Separation from Service") and, except as provided under Section 10(b) of this Agreement, any such amount shall be paid, or in the case of installments, commence payment, on the sixtieth (60<sup>th</sup>) day following Executive's Separation from Service. Any installment payments that would have been made to Executive during the sixty (60) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the sixtieth (60<sup>th</sup>) day following Executive's Separation from Service and the remaining payments shall be made as provided in this Agreement.

(b) Specified Employee. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed at the time of his or her separation from service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (a) the expiration of the six (6)-month period measured from the date of Executive's Separation from Service or (b) the date of Executive's death. Upon the first day of the seventh month following the date of the Executive's separation from service, all payments deferred pursuant to this Section 10(b) shall be paid in a lump sum to Executive, and any remaining payments due under this Agreement shall be paid as otherwise provided herein.

- 15 -

(c) <u>Expense Reimbursements</u>. To the extent that any reimbursements payable pursuant to this Agreement are subject to the provisions of Section 409A, any such reimbursements payable to Executive pursuant to this Agreement shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(d) <u>Installments</u>. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment.

11. <u>Definition of Terms</u>. The following terms referred to in this Agreement shall have the following meanings:

(a) <u>Affiliates</u>. "Affiliates" means any of the Company's subsidiaries or joint ventures currently existing or which shall be established during Executive's employment by the Company.

(b) <u>Bona Fide Offer of Employment</u>. "Bona Fide Offer of Employment" means an offer to provide services in any capacity to another Person that during the first twelve (12) months of providing such services shall entitle Executive to earn a base salary that equals or exceeds Executive's annual Base Salary in effect as of his termination date.

(c) <u>Cause</u>. "Cause" means the occurrence of any of the following events, as determined by the Board or a committee designated by the Board, in its sole discretion: (i) Executive's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) Executive's attempted commission of, or participation in, a fraud against the Company; (iii) Executive's intentional, material violation of any contract or agreement between Executive and the Company or of any statutory duty owed to the Company, including this Agreement; (iv) Executive's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) Executive's gross misconduct.

(d) Change in Control. "Change in Control" means:

*Ownership*. Any "Person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities (excluding for this purpose any such voting securities held by the Company or its Affiliates or by any employee benefit plan of the Company) pursuant to a transaction or a series of related transactions which the Board of Directors does not approve; or

- 16 -

*Merger/Sale of Assets.* (A) A merger or consolidation of the Company whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) more than 50% of the total voting power represented by the voting securities of the Company or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or (B) the sale or disposition by the Company of all or substantially all of the Company's assets in a transaction requiring stockholder approval Notwithstanding the foregoing, a "Change in Control" must also constitute a "change in control event" as defined in Treasury Regulation §1.409A-3(i)(5).

(e) <u>Change in Control Period</u>. "Change in Control Period" means the period beginning with the agreement which if consummated is a Change in Control and ending twelve (12) months after the effective date of a Change in Control.

(f) <u>Covered Termination</u>. "Covered Termination" shall mean the termination of Executive's employment (i) by the Company other than for Cause, or (ii) by Executive for Good Reason.

(g) <u>Competing Entity</u>. "Competing Entity" shall mean (i) the following entities: Ablynx, Affibody, Affilogic, F-Star, Macrogenics, Merus, Molecular Partners, Xencor; and (ii) any other Person engaged or actively planning to be engaged in the business of developing, manufacturing and marketing next generation protein therapeutics for respiratory, asthma, autoimmune and oncology conditions.

(h) <u>Competing Position</u>. "Competing Position" shall mean engaging, directly or indirectly, in any manner or capacity (whether for compensation or not), as adviser, principal, agent, affiliate, promoter, partner, officer, director, employee, stockholder, owner, co-owner, consultant, or member of any association or otherwise, in any Competing Entity. Notwithstanding the foregoing, "Competing Position" shall not include Executive's employment, engagement, or other association with a Competing Entity in a division, unit or segment of the Competing Entity that is not engaged or actively planning to be engaged in the business of developing, manufacturing and marketing next generation protein therapeutics for respiratory, asthma, and autoimmune oncology conditions, *provided however*, that Executive (i) first provides the Company with a written notice describing in reasonable detail the position with and anticipated activities for the Competing Entity, which written notice also includes an assurance that Executive's affiliation with and services for the Competing Entity shall relate only to the non-competitive division, unit or segment and shall not involve any activities that are competing Entity will not require or cause Executive to use or disclose the Company's Confidential Information.

- 17 -

(i) <u>Good Reason</u>. "Good Reason" means Executive's resignation from all positions he or she then holds with the Company if, without Executive's consent: (i) (A) there is a material diminution in Executive's duties and responsibilities with the Company or in job title; (B) there is a material reduction of Executive's base salary; *provided*, *however*, that a material reduction in Executive's base salary pursuant to a salary reduction program affecting all or substantially all of the employees of the Company and that does not adversely affect Executive to a greater extent than other similarly situated employees shall not constitute Good Reason; or (C) Executive is required to relocate Executive's primary work location to a facility or location that would increase Executive's one-way commute distance by more than fifty (50) miles from Executive's primary work location as of immediately prior to such change, (ii) Executive provides written notice outlining such conditions, acts or omissions to the Company within thirty (30) days immediately following such material change or reduction, (iii) such material change or reduction is not remedied by the Company within thirty (30) days following the Company's receipt of such written notice and (iv) Executive's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

(j) <u>Good Standing</u>. "Good Standing" means that Executive remains actively employed and (i) has not been given notice of the termination of employment; (ii) has not given notice of resignation or resigned; (iii) is not suspended by the Company for violation of its material policies and/or procedures and (iv) is not under investigation for conduct that could, in the Company's good faith determination, result in a suspension or termination for Cause.

(k) "<u>Person</u>" means without limitation, an individual, a partnership, a limited liability company, a corporation, an association, a joint stock company, a trust, a joint venture, an unincorporated organization and a governmental entity or any department, agency or political subdivision thereof.

# (Signature page follows)

- 18 -

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year set forth below.

# Pieris Pharmaceuticals, Inc.

By: /s/ Stephen S. Yoder

Name: Stephen S. Yoder Title: Chief Executive Officer

# EXECUTIVE

/s/ Claude Knopf

Name: Claude Knopf

Signature Page to Employment Agreement

- 19 -

## CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement") is entered into on February 1, 2017, by and between Pieris Pharmaceuticals, Inc., a Nevada corporation, with its principal place of business being Lise-Meitner-Strasse 30, 85354 Freising-Weihenstephan, Germany (the "Company") and Danforth Advisors, LLC, a Massachusetts limited liability corporation, with its principal place of business being 91 Middle Road, Southborough, MA 01772 ("Danforth"). The Company and Danforth are herein sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, the Company is a U.S. publicly traded company that possesses know-how and proprietary technology related to the field of Anticalin<sup>®</sup> brand proteins; and

WHEREAS, Danforth has expertise in financial and corporate operations and strategy, including financial reporting requirements for U.S. publicly traded companies; and

WHEREAS, Danforth desires to serve as an independent consultant for the purpose of providing the Company with certain strategic and financial advice and support services, as more fully described in Exhibit A attached hereto, (the "Services"); and

WHEREAS, the Company wishes to engage Danforth on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which are hereby acknowledged, the Parties agree and covenant as follows.

1. <u>Services of Consultant</u>. Danforth will assist the Company with matters relating to the Services commencing on the date that Lance Thibault is appointed as the Acting Chief Financial Officer of the Company (the "Effective Date"). The Services are more fully described in <u>Exhibit A</u> attached hereto. Danforth and the Company will review the Services on a monthly basis to prioritize and implement the tasks listed on <u>Exhibit A</u>.

2. <u>Compensation for Services</u>. In full consideration of Danforth's full, prompt and faithful performance of the Services, the Company shall compensate Danforth a consulting fee more fully described in <u>Exhibit A</u> (the "Consulting Fee"). Danforth shall, from time to time, but not more frequently than twice per calendar month, invoice the Company for Services rendered, and such invoice will be paid upon fifteen (15) days of receipt. Each month the Parties shall evaluate jointly the current fee structure and scope of Services. Danforth reserves the right to an annual increase in consultant rates of up to 4%, effective January 1 of each year. Upon termination of this Agreement pursuant to Section 3, no compensation or benefits of any kind as described in this Section 2 shall be payable or issuable to Danforth after the effective date of such termination. In addition, the Company will reimburse Danforth for reasonable out-of-pocket business expenses, including but not limited to travel and parking, incurred by Danforth in performing the Services hereunder, upon submission by Danforth of supporting documentation reasonably acceptable to the Company. Any such accrued expenses in any given three (3) month period that exceed one thousand dollars (\$1,000) shall be submitted to the Company for its prior written approval.

All Danforth invoices and billing matters should be addressed to:

Company Accounts Payable Contact:

[NAME] [EMAIL ADDRESS] [PHONE NUMBER] [ADDRESS]

All Company payments and billing inquiries should be addressed to:

Danforth Accounting:

Danforth Advisors PO Box 335 Southborough, MA 01772

3. <u>Term and Termination</u>. The term of this Agreement will commence on the Effective Date and will continue through the anniversary of such date in the next calendar year (the "Term"). This Agreement may be extended for an additional period by mutual written agreement. This Agreement may be terminated by either Party hereto: (a) with Cause (as defined below), upon thirty (30) days prior written notice to the other Party; or (b) without cause upon sixty (60) days prior written notice to the other Party. For purposes of this Section 3, "Cause" shall include: (i) a breach of the terms of this Agreement which is not cured within thirty (30) days of written notice of such default or (ii) the commission of any act of fraud, embezzlement or deliberate disregard of a rule or policy of the Company.

4. Time Commitment. Danforth will devote such time to perform the Services under this Agreement as may reasonably be required.

5. <u>Place of Performance</u>. Danforth will perform the Services at such locations upon which the Company and Danforth may mutually agree. Danforth will not, without the prior written consent of the Company, perform any of the Services at any facility or in any manner that might give anyone other than the Company any rights to or allow for disclosure of any Confidential Information (as defined below).

6. <u>Compliance with Policies and Guidelines</u>. Danforth will perform the Services in accordance with all rules or policies adopted by the Company that the Company discloses in writing to Danforth.

7. <u>Confidential Information</u>. Danforth acknowledges and agrees that during the course of performing the Services, the Company may furnish, disclose or make available to Danforth information, including, but not limited to, material, compilations, data, formulae, models, patent disclosures, procedures, processes, business plans, projections, protocols, results of experimentation and testing, specifications, strategies and techniques, and all tangible and intangible embodiments thereof of any kind whatsoever (including, but not limited to, any apparatus, biological or chemical materials, animals, cells, compositions, documents, drawings, machinery, patent applications, records and reports), which is owned or controlled by the Company and is marked or designated as confidential at the time of disclosure or is of a type that is customarily considered to be confidential information (collectively the "Confidential Information"). Danforth acknowledges that the Confidential Information or any part thereof is the exclusive property of the Company and shall not be disclosed to any third party without first

obtaining the written consent of the Company. Danforth further agrees to take all practical steps to ensure that the Confidential Information, and any part thereof, shall not be disclosed or issued to its affiliates, agents or employees, except on like terms of confidentiality. The above provisions of confidentiality shall apply for a period of five (5) years.

8. Intellectual Property. Danforth agrees that all ideas, inventions, discoveries, creations, manuscripts, properties, innovations, improvements, know-how, inventions, designs, developments, apparatus, techniques, methods, and formulae that Danforth conceives, makes, develops or improves as a result of performing the Services, whether or not reduced to practice and whether or not patentable, alone or in conjunction with any other party and whether or not at the request or upon the suggestion of the Company (all of the foregoing being hereinafter collectively referred to as the "Inventions"), shall be the sole and exclusive property of the Company. Danforth hereby agrees in consideration of the Company's agreement to engage Danforth and pay compensation for the Services rendered to the Company and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged that Danforth shall not, without the prior written consent of the Company, directly or indirectly, consult for, or become an employee of, any company which conducts business in the Field of Interest anywhere in the world. As used herein, the term "Field of Interest" shall mean the research, development, manufacture and/or sale of the products resulting from the Company's technology. The limitations on competition contained in this Section 8 shall continue during the time that Danforth performs any Services for the Company, and for a period of three (3) months following the termination of any such Services that Danforth performs for the Company. If any part of this section should be determined by a court of competent jurisdiction to be unreasonable in duration, geographic area, or scope, then this Section 8 is intended to and shall extend only for such period of time, in such area and with respect to such activity as is determined to be reasonable. Except as expressly provided herein, nothing in this Agreement shall preclude Danforth from consulting for or being employed by any other person or entity.

9. <u>Non Solicitation</u>. All personnel representing Danforth are employees or contracted agents of Danforth. As such, they are obligated to provide the Services to the Company and are obligated to Danforth under confidentiality, non-compete, and non-solicitation agreements. Accordingly, they are not retainable as employees or contractors by the Company and the Company hereby agrees not to solicit, hire or retain their services for so long as they are employees or contracted agents of Danforth and for two (2) years thereafter. Should the Company violate this restriction, it agrees to pay Danforth liquidated damages equal to equal to thirty percent (30%) of the employee's starting annual base salary and target annual bonus for each Danforth contracted agent hired by the Company in violation of this Agreement, plus Danforth's reasonable attorneys' fees and costs incurred in enforcing this agreement should the Company fail or refuse to pay the liquidated damages amount in full within thirty (30) days following its violation.

10. <u>Placement Services</u>. In the event that Danforth refers a potential employee to the Company and that individual is hired, Danforth shall receive a fee equal to ten percent (10%) of the employee's starting annual base salary. This fee is due and owing whether an individual is hired, directly or indirectly on a permanent basis or on a contract or consulting basis by the Company, as a result of Danforth's efforts within one (1) year of the date applicant(s) are submitted to the Company. Such payment is due within thirty (30) days of the employee's start date.

11. No Implied Warranty. Except for any express warranties stated herein, the Services are provided on an "as is" basis, and the Company disclaims any and all other warranties, conditions, or representations (express, implied, oral or written), relating to the Services or any part thereof. Further, in performing the Services Danforth is not engaged to disclose illegal acts, including fraud or defalcations, which may have taken place. The foregoing notwithstanding, Danforth will promptly notify the Company if Danforth becomes aware of any such illegal acts during the performance of the Services. Because the Services do not constitute an examination in accordance with standards established by the American Institute of Certified Public Accountants (the "AICPA"), Danforth is precluded from expressing an opinion as to whether financial statements provided by the Company are in conformity with generally accepted accounting principles or any other standards or guidelines promulgated by the AICPA, or whether the underlying financial and other data provide a reasonable basis for the statements.

12. Indemnification. Each Party hereto agrees to indemnify and hold the other Party hereto, its directors, officers, agents and employees harmless against any claim based upon circumstances alleged to be inconsistent with such representations and/or warranties contained in this Agreement. Further, the Company shall indemnify and hold harmless Danforth and any of its subcontractors against any claims, losses, damages or liabilities (or actions in respect thereof) that arise out of or are based on the Services performed hereunder, except for any such claims, losses, damages or liabilities arising out of the gross negligence or willful misconduct of Danforth or any of its employees or subcontractors. The Company will endeavor to add Danforth and any applicable employee or subcontractor to its insurance policies as additional insureds, including without limitation the Company's Directors and Officers liability insurance.

13. Independent Contractor. Danforth and its employees and subcontractors are not, nor shall any of them be deemed to be at any time during the term of this Agreement, an employee of the Company, and therefore neither Danforth nor its employees or subcontractors shall be entitled to any benefits provided by the Company to its employees. Danforth's status and relationship with the Company shall be that of an independent contractor and consultant. Danforth shall not state or imply, directly or indirectly, that Danforth is empowered to bind the Company without the Company's prior written consent. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties. Danforth will be solely responsible for payment of all federal, state and local taxes and contributions imposed or required on income, and for all unemployment insurance, social security contributions and all other charges and taxes arising from this Agreement and the use of any of Danforth's employees or subcontractors to perform services under this Agreement.

14. <u>Records</u>. Upon termination of Danforth's relationship with the Company, Danforth shall deliver to the Company any property or Confidential Information of the Company relating to the Services which may be in its possession including products, project plans, materials, memoranda, notes, records, reports, laboratory notebooks, or other documents or photocopies and any such information stored using electronic medium.

15. <u>Notices</u>. Any notice under this Agreement shall be in writing (except in the case of verbal communications, emails and teleconferences updating either Party as to the status of work hereunder) and shall be deemed delivered upon personal delivery, one day after being sent via a reputable nationwide overnight courier service or two days after deposit in the mail or on the next business day following transmittal via facsimile. Notices under this Agreement shall be sent to the following representatives of the Parties:

If to the Company:

Name:	Stephen Yoder		
Title:	Chief Executive Officer		
Address:	Lise-Meitner-Strasse 30		
	85354 Freising-Weihenstephan		
	Germany		
		Phone:	
		E-mail:	

If to Danforth:

Name:	Gregg Beloff
Title:	Managing Director

Address: Phone: E-mail:

16. <u>Assignment and Successors</u>. This Agreement may not be assigned by a Party without the consent of the other which consent shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation.

17. <u>Force Majeure</u>. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of either Party. In the event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

18. <u>Headings</u>. The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

19. <u>Integration</u>; <u>Severability</u>. This Agreement is the sole agreement with respect to the subject matter hereof and shall supersede all other agreements and understandings between the Parties with respect to the same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.

20. <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, excluding choice of law principles. The Parties agree that any action or proceeding arising out of or related in any way to this Agreement shall be brought solely in a Federal or State court of competent jurisdiction sitting in the Commonwealth of Massachusetts.

21. <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one agreement.

If you are in agreement with the foregoing, please sign where indicated below, whereupon this Agreement shall become effective as of the Effective Date.

DANFORTH ADVISORS, LLC

PIERIS PHARMACEUTICALS, INC.

By:	/s/ Gregg Beloff	By:	/s/ Stephen S. Yoder
Print Name:	Gregg Beloff	Print Name:	Stephen Yoder
Title:	Managing Director	Title:	Chief Executive Officer
Date:	1/24/17	Date:	27 January 2017

# EXHIBIT A

# Description of Services and Schedule of Fees

Danforth will perform mutually agreed to finance and accounting functions (the "Services") which are necessary to support the management and operations of the Company, certain of which are set forth below.

# CFO Services:

- · Ensure compliance with SEC filing and other regulatory requirements, and manage related systems
  - Preparation and/or review of periodic SEC filings
  - Certification of SEC filings, as the principal financial officer and principal accounting officer commencing with the Form 10-K for the year ended December 31, 2016
- · Leadership of investor relations activities
  - Participation in quarterly earnings calls
  - Participation in drafting investor communications (press releases, annual report, etc.)
  - Meetings/calls with investor community and analysts, as appropriate
  - Develop and execute strategy for improving liquidity of Pieris' stock
- Oversee the finance and accounting functions
  - Management of accounting and finance team
  - Establish priorities
  - Review of internal control procedures, systems and resources to ensure propriety and adequacy
- Board, Audit, Compensation, and Corporate Governance committee meeting preparation, support and attendance

- Management of treasury function
  - Currency matters
  - Banking relationships

- Investment policy
- Risk management and insurance
- Participate in longer-term strategic planning process
- · Provide financial support for strategic business planning and business development/licensing opportunities
- · Participate in financing activities, including additional capital raises and/or debt and equity restructurings
- Perform financial modeling, planning and analysis
- Strategic opportunity assessment
- Stock option plan management

The Services provided above will be provided by Lance Thibault who shall be appointed as Acting Chief Financial Officer of the Company. Recognizing the need to prioritize activities and refine the definition and scope of the Services to be provided, Danforth shall review the list of Services with the Company's CEO on a periodic basis to ensure alignment and establish clear expectations.

# **Financial Terms:**

Danforth will provide the Services outlined for an hourly fee, as follows:

# CFO: Lance Thibault \$300/hour

The Services shall be provided for a minimum of six months, beginning on the Effective Date.

Travel time will be charged at \$150 per hour, and in no event will travel time be charged for more than six hours per day. In additional, the Company will reimburse Danforth for reasonable out-of-pocket business expenses to the extent set forth in Section 2 of the Agreement.

## Equity Compensation: To Be Discussed

The Company shall in the sole discretion of its Board of Directors consider whether or not to grant equity to Danforth in an amount commensurate with similar positions at similar companies, and reflective of the duration of the assignment.

#### PIERIS PHARMACEUTICALS, INC.

## NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Board of Directors of Pieris Pharmaceuticals, Inc. (the "<u>Company</u>") has approved the following Non-Employee Director Compensation Policy (this "<u>Policy</u>") which establishes compensation to be paid to non-employee directors of the Company, effective as of January 1, 2017 ("<u>Effective Time</u>"), to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

## **Applicable Persons**

This Policy shall apply to each director of the Company who is not an employee of the Company or any Affiliate (each, a "<u>Non-Employee Director</u>"). "<u>Affiliate</u>" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

### **Stock Option Grants**

All stock option amounts set forth herein shall be subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock.

### Annual Stock Option Grants

Annually, each Non-Employee Director shall be granted a non-qualified stock option to purchase 20,000 shares of the Company's common stock under the Company's 2014 Stock Incentive Plan (the "Stock Plan") on January 25 of each year.

#### Initial Stock Option Grant For Newly Appointed or Elected Directors

Each new Non-Employee Director shall be granted a non-qualified stock option to purchase 30,000 shares of the Company's common stock under the Stock Plan at the first regularly scheduled meeting of the Board of Directors on or after his or her initial appointment or election to the Board of Directors.

## Terms for All Option Grants

Unless otherwise specified by the Board of Directors or the Compensation Committee at the time of grant, all options granted under this Policy shall (i) vest in equal quarterly installments at the end of each quarter following the grant date until the end of the fiscal year in which the grant was made, subject to the Non-Employee Director's continued service on the Board of Directors; (ii) have an exercise price equal to the fair market value of the Company's common stock as determined in the Stock Plan on the grant date; (iii) terminate ten years after the grant date and (iv) contain such other terms and conditions as set forth in the form of option agreement approved by the Board of Directors or the Compensation Committee prior to the grant date.

### **Annual Fees**

Each Non-Employee Directors serving on the Board of Directors and the Audit Committee, Compensation Committee and/or Nominating and Corporate Governance Committee, as applicable, shall be entitled to the following annual amounts (the "<u>Annual Fees</u>"):

Board of Directors or Committee of Board of Directors	Retainer Amount • Member	Annual Retainer Amount for Chair	
Board of Directors	\$ 35,000	\$	25,000
Audit Committee	\$ 7,500	\$	15,000
Compensation Committee	\$ 5,000	\$	10,000
Nominating and Corporate Governance Committee	\$ 3,750	\$	7,500

Except as otherwise set forth in this Policy, all Annual Fees shall be paid for the period from January 1 through December 31 of each year. Such Annual Fees shall be paid in cash or a grant of an option to purchase common stock under the Stock Plan, at the election of each Non-Employee Director, as follows:

- cash in the amount of each Non-Employee Director's Annual Fees; or
- an option to purchase such number of shares of the Company's common stock as is equal to the full dollar amount of each Non-Employee Director's Annual Fees (as calculated below under "Calculation of Shares and Grant Terms"); or

## Election

Each Non-Employee Director shall make an annual election on the form provided by the Company, indicating the combination of cash and/or common stock elected in the year prior to the payment, indicating his or her election for the following fiscal year. If no election has been made prior to the first date of fiscal year, then the Non-Employee Director shall receive all Annual Fees in cash. Each newly elected or appointed Non-Employee Director shall make an election prior to the beginning of the next calendar quarter after his or her initial appointment or election.

## Payments

Payments payable to Non-Employee Directors shall be paid quarterly in arrears promptly following the end of each fiscal quarter, provided that (i) the amount of such payment shall be prorated for any portion of such quarter that such director was not serving on the Board or a committee and (ii) no fee shall be payable in respect of any period prior to the date such director was elected to the Board or a committee.

## Calculation of Shares and Grant Terms

If an option to purchase shares of common stock are to be received as payment, the number of shares underlying such option shall equal the Black Scholes value of the options computed in accordance with FASB Topic 718 on the 25th day of the month following the end of each fiscal quarter (the "<u>Calculation Date</u>") (rounded down to the nearest whole number so that no fractional shares shall be issued). The option shall be automatically and without any further action required by the Board of Directors issued as of the Calculation Date.

### Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and committees thereof or in connection with other business related to the Board of Directors.

## Amendments

The Compensation Committee shall periodically review this Policy to assess whether any amendments in the type and amount of compensation provided herein should be made and shall make recommendations to the Board of Directors for its approval of any amendments to this Policy.

# Subsidiaries

Entity Pieris Pharmaceuticals GmbH Pieris Australia PTY Ltd. Jurisdiction of Organization

Germany Australia

### **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-204487) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan,
- (2) Registration Statement (Form S-8 No. 333-209308) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan Inducement Stock Option Award for Louis Matis, M.D.,
- (3) Registration Statement (Form S-8 No. 333-213771) pertaining to the Pieris Pharmaceuticals, Inc. 2016 Employee, Director and Consultant Equity Incentive Plan,
- (4) Registration Statement (Form S-3 No. 333-211844),
- (5) Registration Statement (Form S-3 No. 333-212439) and
- (6) Registration Statement (Post-Effective Amendment to FORM S-1 ON FORM S-3 No. 333-202123)

of our report dated March 29, 2017, with respect to the consolidated financial statements of Pieris Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Pieris Pharmaceuticals, Inc. for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Boston, Massachusetts March 29, 2017

### **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Forms S-3 and S-3/A No. 333-212439) pertaining to the offering and resale by selling stockholders, including their transferees, pledges or donees, of up to 13,102,084 shares of the common stock of Pieris Pharmaceuticals, Inc.,
- (2) Registration Statements (Forms S-3 and S-3/A No. 333-211844) pertaining to the registration of up to \$100,000,000 of common stock or preferred stock upon conversion of or exchange for debt securities; common stock upon conversion of or exchange for the preferred stock; common stock, preferred stock or debt securities upon the exercise of warrants, rights units or performance of purchase contracts; or any combination of these securities upon the performance of purchase contracts,
- (3) Registration Statement (Form S-8 No. 333-213771) pertaining to the Pieris Pharmaceuticals, Inc. 2016 Employee, Director and Consultant Equity Incentive Plan,
- (4) Registration Statement (Form S-8 No. 333-209308) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan and Inducement Stock Option Award for Louis Matis, M.D.,
- (5) Registration Statement (Form S-8 No. 333-204487) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan;
- (6) Registration Statement (Post-Effective Amendment to Form S-1 filed on Form S-3 No 333.202123) and related prospectus of Pieris Pharmaceuticals, Inc. for the registration of 15,250,634 shares of its common stock;

of our report dated March 23, 2016, with respect to the consolidated financial statements of Pieris Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Pieris Pharmaceuticals, Inc. for the year ended December 31, 2015.

/s/ Dr. Napolitano Wirtschaftsprüfer [German Public Auditor] /s/ Christ Wirtschaftsprüfer [German Public Auditor]

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Munich, Germany March 29, 2017

#### I, Stephen S. Yoder, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

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 registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Dated: March 29, 2017

/s/ Stephen S. Yoder

Stephen S. Yoder Title: Chief Executive Officer and President (principal executive officer)

#### I, Lance Thibault, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

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 registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Dated: March 29, 2017

/s/ Lance Thibault

Lance Thibault Title: Acting Chief Financial Officer (principal financial officer)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2016 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2017

/s/ Stephen S. Yoder

Stephen S. Yoder Title: Chief Executive Officer and President (principal executive officer)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2016 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2017

/s/ Lance Thibault

Lance Thibault Title: Acting Chief Financial Officer (principal financial officer)