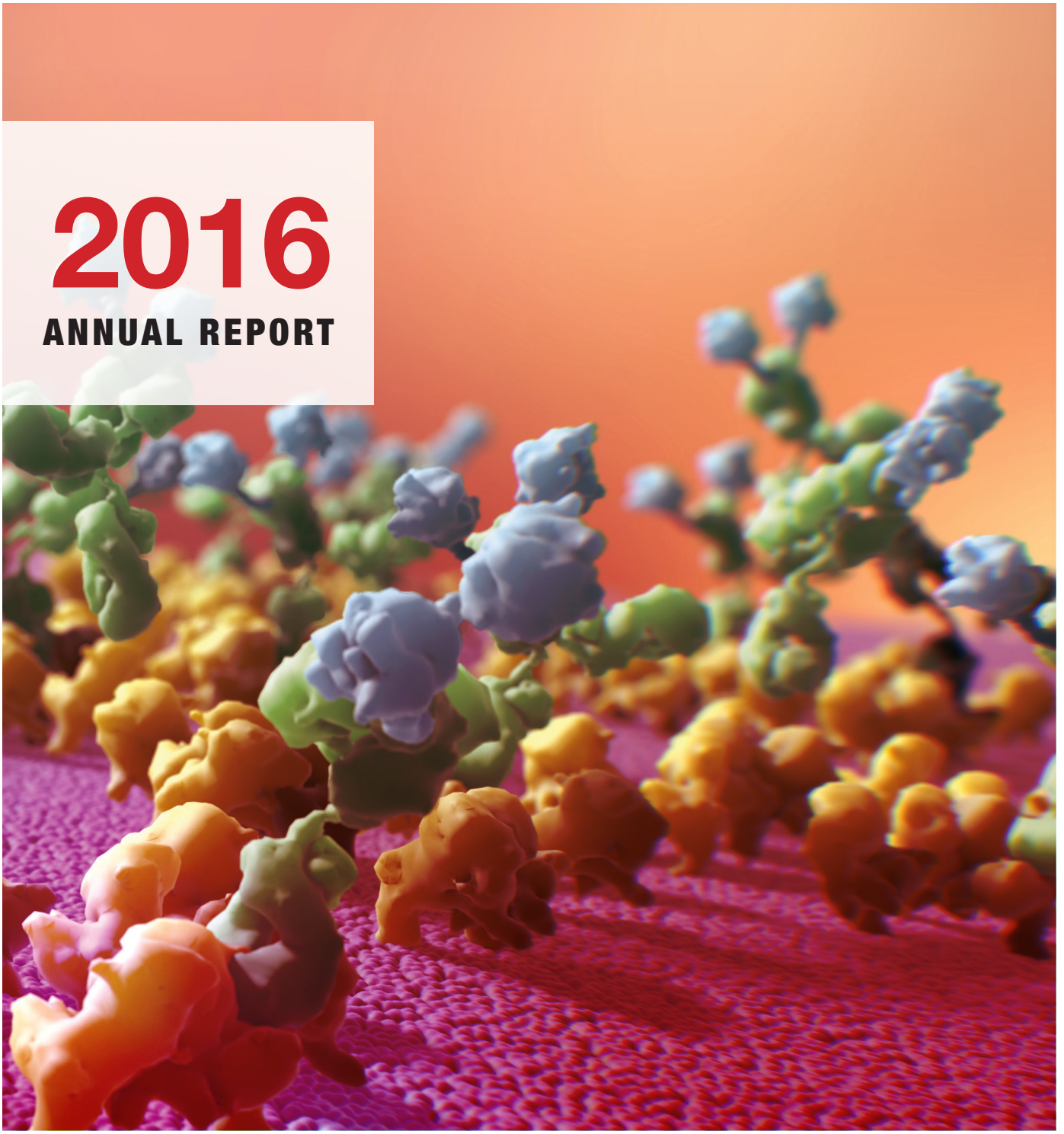
2016
ANNUAL REPORT



pieris
PHARMACEUTICALS

Dear Shareholders, Employees and Friends,

2016 was a highly productive and formative year for Pieris, a period of advancing key initiatives that laid the foundation for our transformation into a fully-integrated drug development and commercial organization, which we're experiencing on an accelerated basis in 2017. Indeed, the two significant partnerships we announced in the first half of 2017—with Servier in immuno-oncology (IO) and AstraZeneca in respiratory diseases—are the product of these efforts, and we're pleased to increase our focus on these two immunology-related therapeutic areas, now the two key value-driving pillars of our company.

Pieris' overall strategy for building value for our shareholders is to maintain a balance between advancing our proprietary pipeline of unique Anticalin® therapeutics and engaging in strategic partnerships with industry leaders, while diversifying across multiple, high-value therapeutic areas with differentiated drug candidates. Our accomplishments in 2016 included broad development progress across our proprietary clinical and preclinical pipeline, the achievement of several milestones in our collaborative programs, the expansion of our management team and Board of Directors and the completion of a $16.5 million private placement that strategically improved our shareholder base and increased our financial strength while engaging then-prospective partners for company-transforming collaborations.

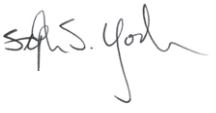
We made material progress advancing our proprietary pipeline of drug candidates in 2016 which paved the way for our new partnerships. As a key example, we had the opportunity to present positive data on our lead bispecific drug candidate for immuno-oncology, PRS-343, at the CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in September 2016. Although PRS-343 deliberately remains fully proprietary, as the key value driver for our company in the near term, this program showcases our unique bispecifics capabilities and catalyzed our strategic partnership with Servier to advance other unique IO bispecific programs. For PRS-080, the most advanced program in our pipeline, Pieris made significant progress, completing dosing of all patients early in 2017 in a Phase Ib trial in dialysis-dependent anemia patients. Shortly thereafter, we signed an exclusive option agreement with Aska Pharmaceutical Company of Japan to license the development and commercial rights to PRS-080 in Japan as well as certain other Asian markets. We, likewise, advanced our lead respiratory candidate, PRS-060, through IND-enabling studies, demonstrating the high-value opportunity for Anticalin® molecules as an inhalable drug class to address respiratory disease, locally, prior to signing a major collaboration with AstraZeneca.

The achievements of 2016 were a prelude to two significant corporate agreements that are, together, transformative for us as a company, underpinning our commitment to becoming an immunology-focused fully integrated biotech company that will market innovative therapies in the USA. In January 2017, we entered into a strategic co-development alliance with Servier in immuno-oncology, in which we will jointly pursue several bispecific therapeutic programs including our proprietary dual checkpoint inhibitor PRS-332. From this deal, we received approximately $31.3 million USD upfront and stand to receive up to approximately $ 1.8 billion USD in milestones in addition to up to low double-digit royalties, while retaining full US commercial rights on several programs, including PRS-332.

Our second major deal of 2017, with the world's leading respiratory company, AstraZeneca, provides yet an increased level of committed funding, milestone potential and royalty income, which speaks to the transformative potential of inhaled biologics to address respiratory diseases locally. The deal itself includes $57.5 million USD in upfront and near-term milestone payments, approximately $2.1 billion USD in milestone payments plus up to double-digit royalties. With retained co-development and co-commercialization opt-in rights on the lead collaborative program, PRS-060, in addition to two of four committed novel research programs, this alliance provides a path in yet another therapeutic area to forward-integrate into a commercial organization.

The trajectory for Pieris has never been more exciting. As always, I want to thank our employees for their outstanding dedication and vision for Pieris and our shareholders for their commitment and support. I look forward to our continued success in 2017.

Sincerely,



Stephen S. Yoder, J.D.
President & Chief Executive Officer

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	**EIN 30-0784346**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
255 State Street, 9th Floor Boston, MA United States	
(Address of principal executive offices)	**02109 (Zip Code)**

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	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	**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 ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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. ☐

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 ☐ Accelerated filer ☐

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

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.

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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," "would," 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®, Anticalin® and Pocket Binding®. 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 "€" 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 €1.00 to U.S. $1.05155 based on www.oanda.com 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 low-molecular 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® 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® technology and platform were developed in Germany, and we have collaboration arrangements with major multi-national 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 Anticalin-based 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 un-blinding 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.

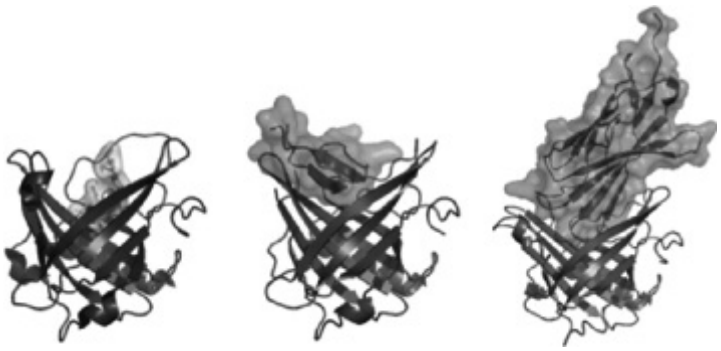
Anticalin platform technology

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	Upcoming Milestone(s)	Commercial Rights
PRS-080 targeting Hepcidin	FID, Anemia of chronic kidney disease	Preclinical – IND Enabling Studies – Phase 1b/2a	■ Planned disclosures of blinded data from Phase Ib in patients in second half of 2017 ■ Planned Phase 2a study to begin in 2017	Pieris
PRS-343 targeting CD137 (4-1BB) and HER2	Immuno Oncology	Preclinical – IND Enabling Studies	■ Planned Phase I clinical study to begin in first half of 2017	Pieris
PRS-060 targeting IL-4RA	Asthma	Preclinical – IND Enabling Studies	■ Expect to complete IND Enabling Studies in 2017 ■ Planned Phase I clinical study to begin in 2017	Pieris
PRS-332 targeting an undisclosed checkpoint target	Immuno Oncology	Preclinical	■ Expect to nominate a development candidate and initiate IND-enabling activities in 2017	Pieris = US Servier = Rest 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.

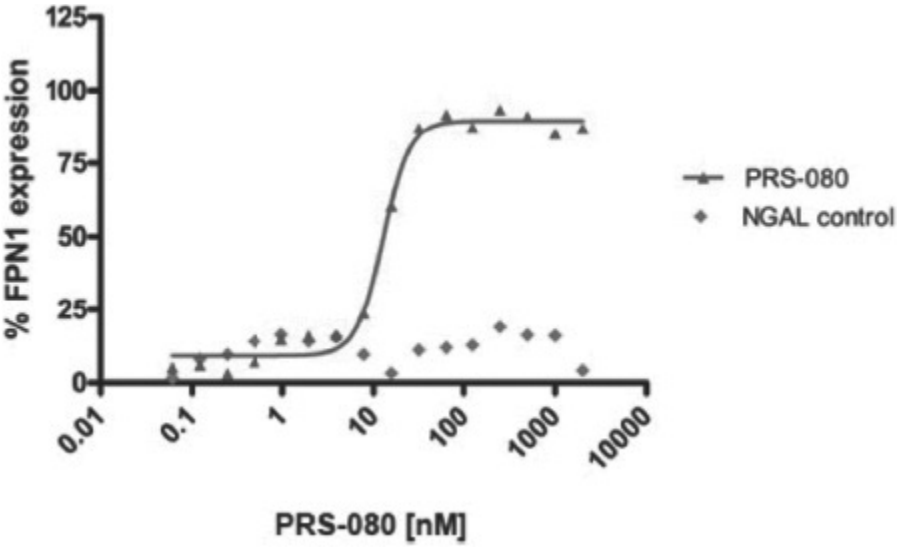
In patients suffering from anemia of CKD, and specifically in patients with FID, hepcidin is chronically produced by the body in abnormally large amounts. Therefore, we believe that the best way to inhibit its function is to administer an inhibitor on a repeated basis, such as once a week. Our approach 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.

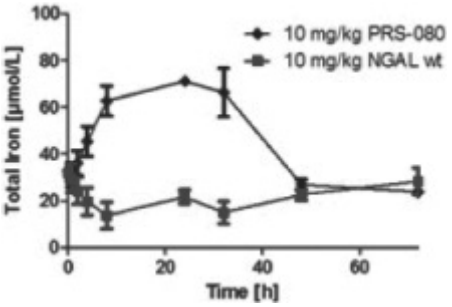
Hepcidin binds to ferroportin and induces its internalization and subsequent degradation, thus disabling iron mobilization from cells. PRS-080 binds strongly to hepcidin and inhibits its activity as shown in potency assays. These in vitro potency studies showed that the hepcidin-induced internalization 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:

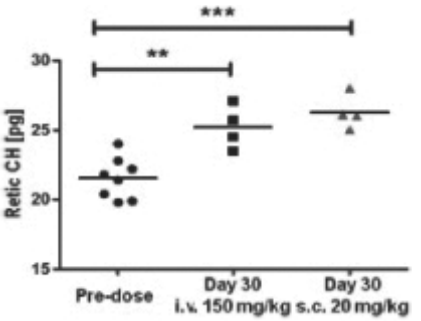


We then studied the functional consequences of hepcidin inhibition on iron mobilization in cynomolgus monkeys. A dose of 1 mg/kg PRS-080 produced a robust, transient and reversible increase in total iron levels from approximately 36 µM at baseline to 52 µM after 8 hours. Doses higher than 1 mg/kg elevated 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).



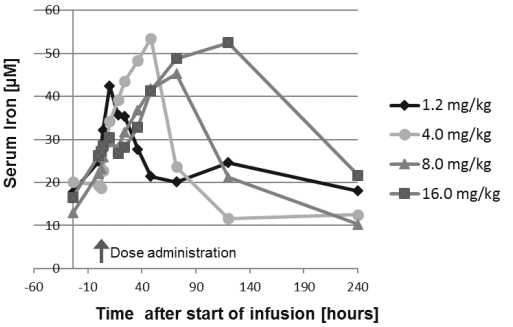
The PK properties of PRS-080 were investigated in cynomolgus monkeys after a single administration at doses ranging from 20 mg/kg to 150 mg/kg. The concentration over time profiles of PRS-080 showed standard drug-like properties, as the kinetics were dose proportional and there was a low volume of distribution. 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.



Time to Peak
Duration of Response
Peak Iron Concentration

Dose [mg/kg]	1.2	4.0	8.0	16.0
Time to peak iron concentration	10h	48h	72h	120h
Duration of iron response*	25h	64h	94h	185h
Peak serum iron concentration [µM]	42.5	53.6	45.2	52.2

* Estimated time point where serum iron falls <34.5 µM

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 with results being available by the end 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, super-family. 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 Fcγ receptor-positive cells, which are not selectively tumor-localized but distributed throughout the body for Fcγ-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.

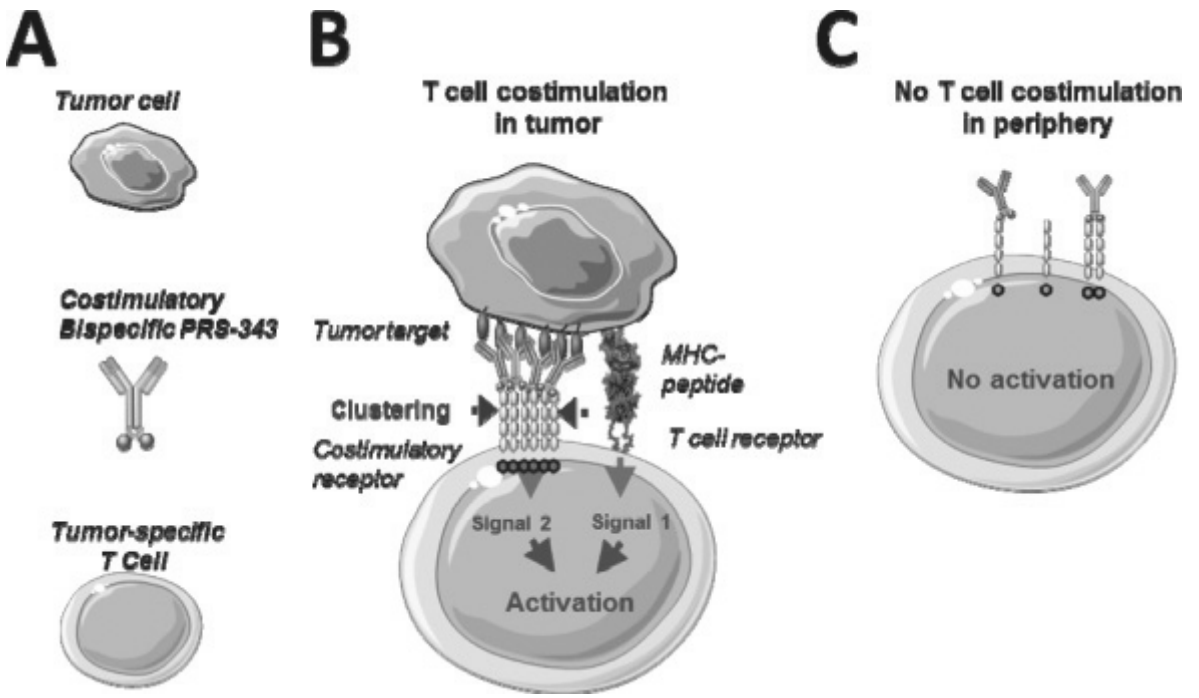


Figure 1 Concept of costimulatory T cell engagement. (A) The elements of the system are a target-positive tumor cell, a T cell with a TCR that is specific for an HLA/peptide combination on the tumor, and a costimulatory bispecific. (B) Within a patient´s tumor, tumor-specific T cells are bridged with 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.

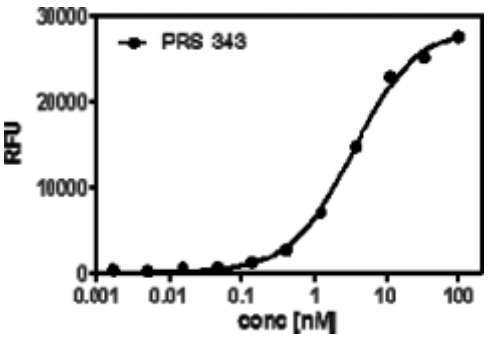


Figure 2 PRS-343 simultaneous binding to targets HER2 and CD137. Recombinant Her2 was coated on a microtiter plate, followed by titration of PRS-343. Subsequently, a constant concentration of biotinylated human CD137 was added, which was detected via a peroxidase-conjugated avidin variant, ExtrAvidin®.

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.

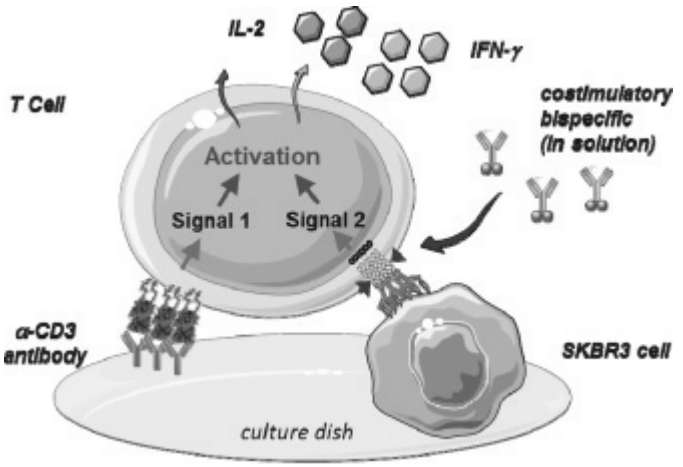


Figure 3 Visualization of costimulatory T cell activation assay. HER2-positive tumor cells are grown overnight on cell culture plates that have been precoated with low amounts of an anti-CD3 antibody to provide a limited primary activation of T cells via the T cell receptor**.** T cells are added to 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-γ levels in the culture supernatants after continued culture.*

There is a clear induction of IL-2 (Figure A) and IFN- γ (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-γ 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-γ induction almost completely, except at the highest concentrations of PRS-343 employed (Figure B and Figure D).

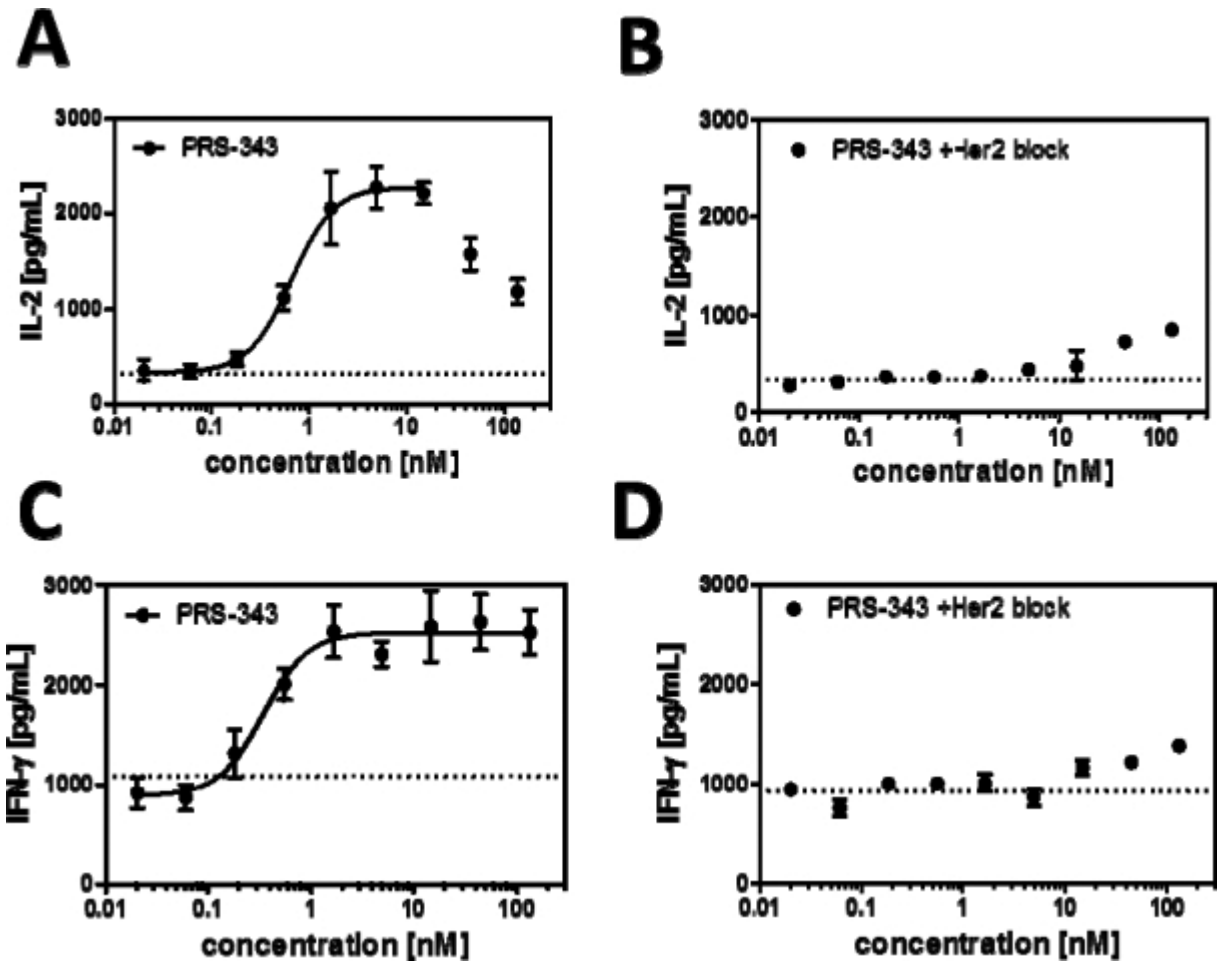


Figure 4 Experimental result of costimulatory T cell activation assay. HER2-positive SKBR3 tumor cells were grown overnight on 96-well plates that had been precoated with 0.25 µg/mL anti-CD3 antibody for 1 h at 37°C. The next day, T cells purified from healthy donor PBMC were added to the wells together 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-γ, 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-γ (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 sub-mucosal 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

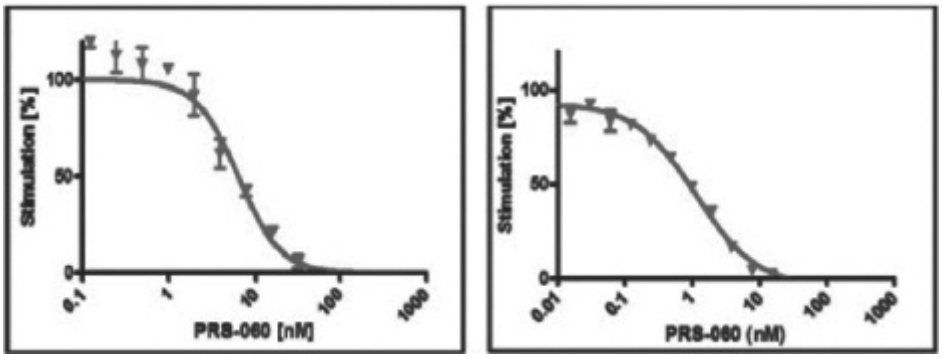
We propose to take PRS-060 forward into clinical trials first in healthy volunteers and then in moderate to severe asthma patients. These trials could accomplish two important goals: we could establish proof-of-concept for inhaled Anticalin proteins, opening up a second route of administration for our 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.

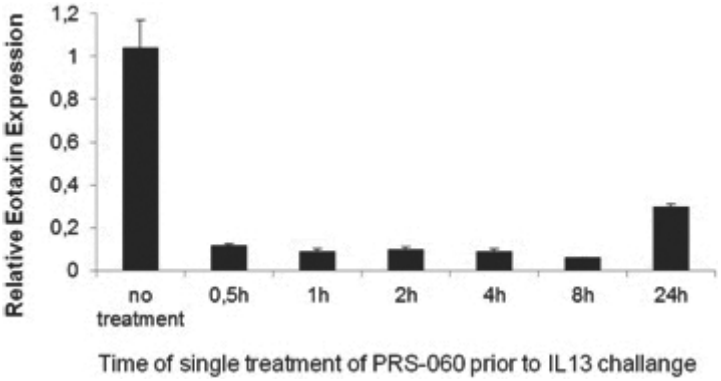
Preclinical data

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:



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, thereby having the potential to elevate immune responses within a tumor microenvironment. We believe that a tethered Anticalin 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®-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 well as three pending provisional patent applications, 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 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®-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 €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 €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 €26.5 million ($27.9 million) in development milestones and up to €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 €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® 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 €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 €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 €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 €0.7 million ($0.7 million). We have the ability to receive up to approximately €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® 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 €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 life-threatening 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 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 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®-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 post-approval 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 collaborations or potential products. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their 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 or in lieu of 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 patents licensed to us under the agreement. Under the Enumeral License Agreement, we can terminate the agreement upon 30 days' notice to Enumeral. Enumeral may terminate the Enumeral License Agreement only upon a material breach by us that is not cured. The loss of the rights licensed to us under our 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, time-consuming 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 employers 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 could have the effect of delaying or preventing changes in control or our management. Any future 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 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 officers to the fullest extent authorized by Nevada law and, subject to certain conditions, to advance the expenses incurred by any director 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 majority-owned 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 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® 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® 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-in-class 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

Name and Principal Position	Year	Salary	Bonus ($)	Option Awards ($) (2)	All other compensation ($)	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

(1) 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 non-compete 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 bi-weekly 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 non-compete 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 whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities 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 following the Company's receipt of such written notice and (iv) the executive's resignation is effective not later than 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	Option exercise price ($)	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	159,961	290,039(3)	$2.80	9/1/2025
Former Chief Financial Officer				
Louis Matis	156,250	343,750(4)	$3.36	8/17/2025
Chief Development Officer				

(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 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.

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 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 held 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 managing member 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 exercise of warrants are excluded from the table above. BVF Partners L.P.,

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."

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and 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's immediate family is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years; (e) the director or a member of the director's immediate family is, or in the past three years has been, employed 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) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description		Incorporated by Reference herein from 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-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-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)	December 18, 2014	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

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PIERIS PHARMACEUTICALS, INC.

Table of Contents

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 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	$(22,799,164)	$(14,058,641)
Net loss per share		
Basic and diluted	$ (0.55)	$ (0.41)
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 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		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total equity
	No. of shares	Share capital	No. of shares	Share capital				
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® 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 terms in the arrangement in making this assessment.

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 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 Anticalin-based 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 oligo-nucleotides. 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 December 31,	
	2016	2015
Domestic	$ (8,724,628)	$ (7,563,300)
Foreign	(13,912,568)	(6,291,475)
Loss before income taxes	$(22,637,196)	$(13,854,775)

The components of the provision (benefit) for income taxes are as follows:

	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 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 €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 €1,050,000 ($1.27 million), the outstanding amount under the repayment agreement, in two tranches as follows: €600,000 ($726,060) plus accrued interest on January 31, 2015 and €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 €931,312 ($1,027,051). The capital gain tax withheld in the amount of €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	$1.91	8.55 years	$—
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, 2016 under the 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 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

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 €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 €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.

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Corporate Information

Board of Directors

Stephen S. Yoder, J.D.
President and Chief Executive Officer

Chau Khuong (Chairman)
Partner, OrbiMed Advisors LLC

Michael Richman
President and Chief Executive Officer, NextCure, Inc.

Julian Adams, Ph.D.
Chief Science Officer, President, Clal Biotechnology Industries Ltd.

Christopher P. Kiritsy
Co-Founder, President and CEO, Arisaph Pharmaceuticals, Inc.

Steven Prelack
Senior Vice President and Chief Operating Officer, VetCor

Jean-Pierre Bizzari, M.D.
Director

Executive Officers

Stephen S. Yoder, J.D.
President and Chief Executive Officer

Lance Thibault
Acting Chief Financial Officer

Louis A. Matis, M.D.
Senior Vice President and Chief Development Officer

Claude Knopf
Senior Vice President and Chief Business Officer

Corporate Headquarters

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Annual Meeting

Friday, June 30, 2017 – 9:00 am
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
666 Third Avenue, 32nd Floor
New York, NY 10017

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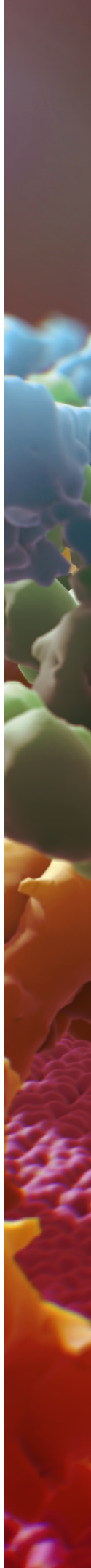
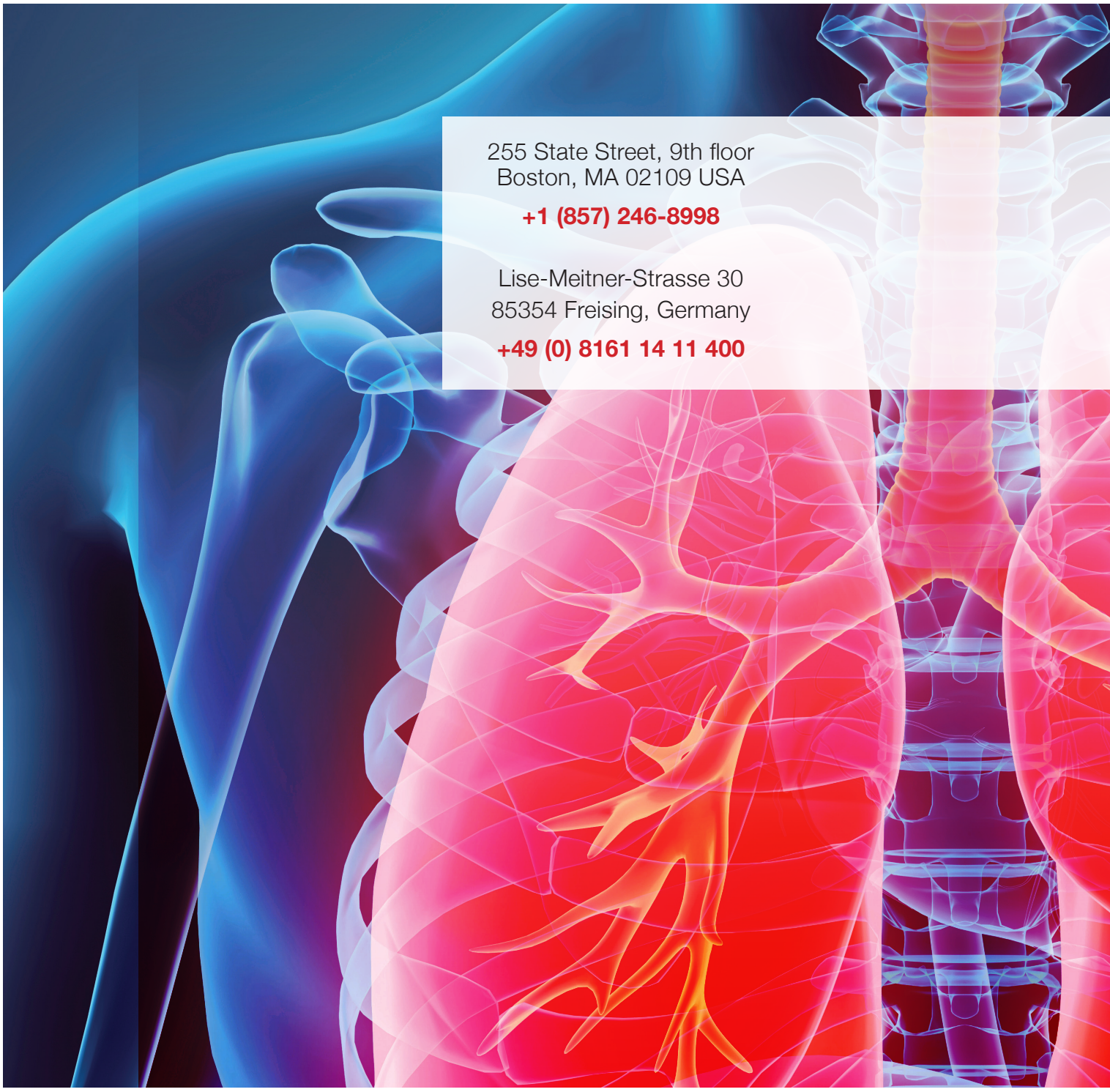
Auditors

Ernst & Young LLP
200 Clarendon Street
Boston, MA 02116

Forward-Looking Statements

This annual report 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 report 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; our liquidity and ability to fund our future operations; 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 annual report, 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, 2016 and the Company's Quarterly Reports on Form 10-Q.





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