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, 2019

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**	**02109**
(Address of principal executive offices)	**(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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**PIRS**	**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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 the registrant's common stock held by non-affiliates of the registrant on June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price on that date of $4.70, was $206,297,429.

As of March 9, 2019, the registrant had 55,212,437 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

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Forward-Looking Statements

This annual report on Form 10-K for the year ended December 31, 2019, or 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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," "approach," "believes," "can," "contemplate," "continue," "look forward," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "suggests," "future," "likely," "goal," "plans," "potential," "projects," "predicts," "seek," "should," "target," "would" or "will" and other similar words or expressions 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 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, and/or limitations;*
- *our plans to research, develop and commercialize our current and future product candidates and Anticalin platform;*
- *our collaborators' election to pursue or continue 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 may 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 Form10-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® and Anticalin®. All other trademarks, trade names and service marks included in this Annual Report on Form10-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, trade dress, or product owner.

As used in this Annual Report on Form10-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, Pieris Australia Pty Ltd., a company organized under the laws of Australia that is a consolidated subsidiary of Pieris Pharmaceuticals GmbH, and Pieris Pharmaceuticals Securities Corporation, a Massachusetts securities corporation, a consolidated subsidiary of Pieris Pharmaceuticals, Inc. 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," "$," "US $" 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. $1.1217 based on Thomson Reuters as of December 31, 2019.

PART I

Item 1. BUSINESS

Corporate History

General

Pieris Pharmaceuticals, Inc. was incorporated in the State of Nevada in May 2013 under the name “Marika Inc.” Pieris Pharmaceuticals, Inc. began operating the business of Pieris Pharmaceuticals GmbH, or Pieris GmbH, through a reverse acquisition on December 17, 2014. Pieris GmbH (formerly Pieris AG, a German company which was founded in 2001) continues as an operating subsidiary of Pieris Pharmaceuticals, Inc.; Pieris Pharmaceuticals, Inc. is the sole stockholder of Pieris GmbH.recent

Pieris Pharmaceuticals, Inc.'s corporate headquarters are located at 255 State Street, 9th Floor, Boston, Massachusetts 02109. The research facilities of Pieris GmbH are located in Hallbergmoos, Germany. Pieris Australia Pty Ltd., a wholly-owned subsidiary of Pieris GmbH, was formed on February 14, 2014 to conduct research and development activities in Australia. Pieris Pharmaceuticals Securities Corporation, a wholly-owned subsidiary of Pieris Pharmaceuticals, Inc. was formed on December 14, 2016 to buy, sell, deal in, or hold securities on its own behalf and not as a broker, and will engage in its activities exclusively for investment purposes.

Business Overview

We are a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Our clinical pipeline includes an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma and an immuno-oncology (IO) bispecific targeting HER2 and 4-1BB. Proprietary to us, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies.

Anticalin proteins are a class of low molecular-weight therapeutic proteins derived from lipocalins, which are naturally occurring proteins typically found in human blood plasma and other bodily fluids. Anticalin proteins function similarly to monoclonal antibodies by binding tightly and specifically to a diverse range of targets. An antibody is a large protein used by the immune system to recognize a target molecule, called an antigen. We believe Anticalin proteins possess numerous advantages over antibodies in certain applications. For example, Anticalin proteins are relatively small in size and comprised of a single polypeptide chain whereas antibodies are much bigger and comprised of four polypeptide chains. The potentially greater stability and smaller size of Anticalin proteins as compared to antibodies potentially enable unique routes of Anticalin protein drug administration such as inhaled delivery. Higher-molecular-weight entities, such as antibodies, are often too large to be delivered effectively through these methods. Our Anticalin technology is modular, which allows us to design multimeric Anticalin-based bi- and multi- specific proteins to bind with specificity to two or more 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 facilitating the killing of 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 best-in-class drugs.

We have intellectual property rights directed to various aspects of our Anticalin technology platform, allowing for further development and advancement of both our platform and drug candidates. We believe that our ownership or exclusive license of intellectual property related to the Anticalin platform provides us with a strong intellectual property position, particularly in cases where we are seeking to address targets and diseases in a novel way and for which there is existing antibody intellectual property. We also believe that the drug-like properties of the Anticalin drug class have been demonstrated in various clinical trials with different Anticalin-based drug candidates, including PRS-060/AZD1402, PRS-343, PRS-080 and others.

Our core Anticalin technology and platform were developed in Germany, and we have collaborations with major multi-national pharmaceutical companies. We entered into a license and collaboration agreement, or the Servier Collaboration Agreement, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, in January 2017 in IO. In May 2017, we entered into an alliance with AstraZeneca AB, or AstraZeneca, to treat respiratory diseases, and in February 2018, we entered into a license and collaboration agreement, or the Seattle Genetics Collaboration Agreement, with Seattle Genetics Inc., or Seattle Genetics, in IO.

In connection with our efforts to develop multispecific Anticalin-based proteins designed to engage immunomodulatory targets, we have gained non-exclusive access to antibody building blocks that can be utilized to develop multispecific antibody-Anticalin fusion proteins.

Our current development plans focus on two core pillars, respiratory diseases and IO.

The lead respiratory Anticalin-based drug candidate, PRS-060/AZD1402, antagonizes IL-4Rα, thereby inhibiting by 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 drive the pathogenesis of asthma and other inflammatory diseases. We believe that the small size and biophysical stability of PRS-060/AZD1402 facilitates direct delivery to the lungs through the use of an inhaler, which may enable high pulmonary concentrations of the drug candidate to be achieved at lower doses than would be reached with antibodies that are systemically delivered. Further, we believe an inhaled drug may be better tolerated than systemically-administered antibodies. We completed a phase 1 single-ascending dose, or SAD, study of PRS-060/AZD1402 and reported in November 2018 that PRS-060/AZD1402 was safe and well-tolerated by healthy volunteers participating in the trial. In October 2019 we reported data from the ongoing multiple ascending dose, or MAD, phase 1 study in mild asthmatics. PRS-060/AZD1402 was safe and well-tolerated by participants in the trial and provided for a robust reduction in fractional exhaled nitric oxide, or FeNO, versus placebo. FeNO is a clinically-validated marker of airway inflammation. Importantly, we were able to show that PRS-060/AZD1402 can inhibit FeNO levels at doses that do not inhibit systemic target engagement, which indicates a localized drug action in the lungs. We anticipate the initiation of a phase 2a study, led by our partner AstraZeneca, for PRS-060/AZD1402 in the second half of 2020.

We are the sponsors of the phase 1 SAD/MAD studies for PRS-060/AZD1402, after which AstraZeneca will be responsible for further clinical development of PRS-060/AZD1402. We have the right to opt-into co-development of PRS-060/AZD1402 with AstraZeneca after completion of the phase 2a study. We also have a separate option to co-commercialize PRS-060/AZD1402 with AstraZeneca in the United States. Beyond PRS-060/AZD1402, our alliance with AstraZeneca includes the development of four inhaled Anticalin-based drug candidates for the treatment of respiratory diseases and three of these programs have been initiated as part of the collaboration: two new programs were initiated in 2018, one program was initiated in 2019. AstraZeneca will have the option to initiate the fourth discovery program in the collaboration this year.

As part of the Company's commitment to building a novel respiratory pipeline, in the fourth quarter of 2019, Pieris entered into research collaboration with the laboratories of University of Pittsburgh Professors Sally Wenzel, MD, and Anuradha Ray, PhD, focused on comprehensive immune phenotyping of severe asthmatic patients. Key objectives of the collaboration include patient stratification strategies for more streamlined development of therapeutic interventions as well as identifying and validating novel asthma targets.. The Company also continues to advance several proprietary discovery-stage respiratory programs. Pieris expects to share data and rationale for advancement of one of its proprietary programs at a medical meeting in the second half of 2020.

The lead IO Anticalin-based drug candidate in our pipeline, PRS-343, is designed to target the immune receptor 4-1BB and the tumor target HER2. PRS-343 is a genetic fusion of a variant of a HER2-targeting antibody with an Anticalin protein specific for 4-1BB. The proposed mode of action of this 4-1BB/HER2 bispecific is to promote 4-1BB clustering by bridging 4-1BB-positive T-cells with HER2-positive tumor cells, thereby providing a potent co-stimulatory signal to tumor antigen-specific T-cells. PRS-343 is intended to localize 4-1BB activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to 4-1BB-targeting antibodies. Patient dosing in a multicenter, open-label, phase 1 dose escalation study commenced in September 2017. The study is designed to determine the safety, tolerability, and potential anti-cancer activity of PRS-343 in patients with advanced or metastatic HER2-positive solid tumors for which standard treatment options are not available, are no longer effective, or are not tolerated, or in patients that have refused standard therapy. Elevated HER2 expression is associated with multiple cancers, including gastroesophageal, bladder, breast, and a range of other tumor types. We presented interim data from the study in a late-breaking presentation at the Society for Immunotherapy of Cancer (SITC) annual meeting on November 9, 2019. At SITC, we reported that PRS-343 was well tolerated and had a favorable safety profile at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types and showed a potent increase in CD8+ T-cell numbers in the tumor microenvironment in patients, indicative of 4-1BB agonism on T-cells. We continue to enroll patients in that study at higher dose cohorts and different dose regimens. We also reported initial data from a phase 1 escalation study of PRS-343 in combination with atezolizumab at our R&D day on November 19, 2019. We reported that PRS-343 in combination with atezolizumab was well tolerated and had a favorable safety profile at all doses tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types and showed a potent increase in CD8+ T-cell numbers in the tumor microenvironment in patients demonstrating a clinical benefit, indicative of 4-1BB agonism on T-cells and a mode of action distinct from atezolizumab alone. We plan to present detailed data from both studies at a medical meeting in the second half of this year.

In January 2017, we initiated a strategic collaboration with Servier to discover and develop multiple Anticalin-based bispecific therapeutics in IO. The lead program in the alliance is PRS-344 (also known as S095012), a PD-L1/4-1BB antibody-Anticalin bispecific, for which we plan to file an investigational new drug application, or IND, in the first half of 2020. Preclinical data for the PRS-344 program were presented at the SITC 2018 Annual Meeting. We achieved two preclinical milestones under the program, one in December 2018 and another in February 2019. We also executed our option to opt-into co-development and U.S. commercialization of PRS-344 during the first quarter of 2019.

In February 2018, we initiated a strategic collaboration with Seattle Genetics to discover and develop up to three Anticalin-based tumor-targeted bispecific therapeutics in IO. As part of the alliance, we have generated and characterized the first tumor-targeting bispecific for further evaluation and development by Seattle Genetics.

We continue to explore opportunities to develop additional differentiated Anticalin-based multispecific therapeutics in IO. We are performing proof of concept and proof of mechanism studies on additional fully proprietary programs to support drug candidate nomination.

Strategy

Our goal is to become a fully-integrated biotechnology company by discovering and developing Anticalin-based therapeutics to target validated disease pathways in unique and transformative ways, and to later commercialize our therapeutic products. 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:

- ***Supporting AstraZeneca in the initiation of PRS-060/AZD1402 phase 2 studies.*** We have reported promising data from our phase 1 SAD study and ongoing MAD study of PRS-060/AZD1402, are completing the ongoing MAD study, and are working with AstraZeneca for drug supply and other preparations for the phase 2a study of PRS-060/AZD1402. We anticipate that AstraZeneca will initiate the study in the second half of this year.

- ***Completing PRS-343 through phase 1 dose escalation study and initiating the next phase of development studies in gastric cancer.*** We presented interim data from the study at a late-breaking presentation at the SITC annual meeting on November 9, 2019. We reported that PRS-343 was well tolerated and had a favorable safety profile at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types and showed a potent increase in CD8+ T-cell numbers in the tumor microenvironment of responders, indicative of 4-1BB agonism on T-cells. Pieris continues to enroll patients in that study at higher dose cohorts and modified dosing schedules and plans to initiate a further trial of the drug candidate in gastric cancer. We also plan to conclude and report complete data from the dose escalation study of PRS-343 in combination with atezolizumab in 2020.

- ***Advancing PRS-344 to initiation of a phase 1 study.*** PRS-344 is currently undergoing IND-enabling activities and we intend to file an IND for the program in the first half of 2020.

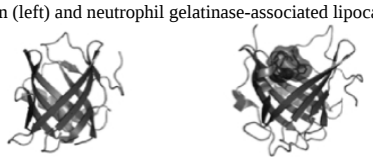
- ***Continuing to build our platform by entering into new partnerships and license and collaborative arrangements and advancing our currently partnered programs.*** We have entered into partnership and collaborative arrangements with pharmaceutical companies in a diverse range of therapeutic areas and geographies. We have active strategic partnerships with the global pharmaceutical companies Servier, AstraZeneca and Seattle Genetics. 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.

- ***Pursuing additional opportunities for our Anticalin technology.*** We intend to continue to identify, vet and pursue opportunities to develop novel Anticalin therapeutics for respiratory diseases, oncology and additional diseases.

- ***Pursuing other platform development activities.*** We continue to make investments in our Anticalin platform, including in display and other technologies used to discover and optimize Anticalin proteins against targets of interest to increase the speed, throughput and quality of the selection process. In addition, we continue to make investments in our platform for the characterization and manufacture of Anticalin proteins to develop drug candidates with excellent drug-like properties that can be efficiently produced.

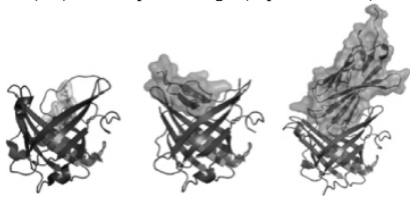
Anticalin Platform Technology

Our platform technology focuses on low molecular-weight Anticalin proteins that can 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 17 to 21 kDa 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 a 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 rigidly conserved beta-barrel backbone with four flexible loops, which, together, form a cup-like binding pocket. The graphic below shows both tear lipocalin (left) and neutrophil gelatinase-associated lipocalin (NGAL, right).



We currently develop our Anticalin proteins from either tear lipocalin, found primarily in human tear fluid as well as the lung epithelium, or NGAL, a protein involved in the innate immune system, by making discrete mutations in the genetic code of the ligand binding regions. These mutations have the potential to lead to highly specific, high-affinity binding proteins for both small and large molecular targets. Mutations are introduced at pre-defined positions, 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. The ability to generate highly-diverse and high-quality Anticalin libraries and to select for the best binders among the large pool of Anticalin proteins by phage display technology gives us the opportunity to select specific and high affinity 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 can be bound more inside the ‘cup’ as well as larger protein targets that can be bound more by the flexible loop region outside of the 'cup'. Our phase 1 studies for PRS-060/AZD1402, our prior phase 1 and 2 studies of PRS-080, our prior phase 1 study of PRS-050, as well as the phase 1 study of a PCSK9-specific Anticalin protein, indicate that these proteins may be non-immunogenic and thereby have the potential to exhibit a favorable safety profile.

The below graphic illustrates Anticalin proteins 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, thereby generating Anticalin libraries suitable for identifying binders to different types of targets. By utilizing bacterial or mammalian expression platforms 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 comprising a single Anticalin protein. Some anticalin-based bi- and multi- specific drug candidates, such as PRS-343 and PRS-344, are expressed in standard mammal expression systems. In this way, 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.

Anticalin proteins share many of the favorable qualities of antibodies, including:

- *High specificity to their targets*. Like 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 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.

- *Scalability for large-scale production*. Like 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 (for example, animal and 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 antibodies, we believe Anticalin proteins offer several advantages over antibodies, including:

- *Small size and biophysical stability*. Anticalin proteins are small in size and are monomeric. Therefore, we believe Anticalin proteins are generally more stable biophysically than antibodies composed of four polypeptide chains, which will potentially enable unique routes of administration, such as pulmonary delivery. Higher-molecular-weight entities such as antibodies are often too large to be formulated and 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 leverage 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.

- *Platform for higher-order multispecificity and avoidance of cross-linking*. Our Anticalin technology allows 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 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 by that do not induce 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 on the same target by genetically linking Anticalin proteins with distinct specificities or by genetic fusion of an Anticalin protein with an antibody. 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. Novel Anticalin proteins genetically fused to each other or to existing antibodies for simultaneous target engagement are expressed as a fusion protein without generally compromising on manufacturability.

- *Flexible formatting facilitates selection of potent T-cell engagers*. The molecular architecture of Anticalin proteins as a single polypeptide chain that folds into a stable eight-stranded β-barrel with exposed N- and C-termini, both not part of the binding site, makes them ideal building blocks to generate bispecific and even multispecific fusion proteins offering novel therapeutic modalities. Multispecific Anticalin-based fusion proteins can be used to pursue innovative therapeutic strategies in IO, particularly by addressing the “immunological synapse” that forms at the interface upon contact between an immune cell and a cancer cell. This can drive an efficient activation of tumor-specific T-cells in the vicinity of the tumor, thereby avoiding some of the toxicities observed with peripheral T-cell activation in healthy tissues. Generally, the formatting flexibility of Anticalin-based biologics offers the ability of modulating valency and geometry of the multispecific compound according to biological needs. For example, Anticalin proteins can be genetically fused to either the N- or C- terminus of the antibody heavy or light chain, thereby resulting in different geometries of the fusion protein with the antibody as well as Anticalin binding sites covering a range of distances with regard to the T-cell target on the one hand and the tumor antigen on the other.

Implementation of the Anticalin Platform Technology: Our Drug Candidate *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:

PRS-060/AZD1402 Targeting IL-4Rα in Asthma

PRS-060/AZD1402 is an Anticalin drug candidate targeting IL-4Rα, a cell surface receptor expressed on immune cells in the lung. IL-4Rα is specific for the cytokine IL-4 and the closely related cytokine IL-13, both key drivers of the immune system. PRS-060/AZD1402 is derived from human tear lipocalin, has a 20 pM affinity for human IL-4Rα and has a favorable stability profile. Following the results reported in the "Clinical data" section below, and presented at the American Thoracic Society International Conference in May 2019 and European Respiratory Society International Congress in October 2019, AstraZeneca and Pieris are preparing to move into a phase 2a study in moderate-to-severe asthmatics in the second half of this year. We believe that PRS-060/AZD1402 represents a first-in-class inhaled biologic targeting IL-4Rα for the treatment of asthma. PRS-060/AZD1402 is being developed in partnership with AstraZeneca, as further described below.

Asthma market

Asthma is a very common chronic airway disorder affecting approximately 300 million people worldwide according to the Global Initiative for Asthma, including approximately 26 million Americans according to the U.S. Centers for Disease Control. Of these 26 million, approximately 7 million are children. Asthma is responsible for 13 million physician visits per year including approximately 2 million emergency visits in the United States, according to the American Lung Association. In the United States between 2008 and 2013, asthma was responsible for approximately $3 billion in losses due to missed work and school days, approximately $29 billion due to asthma-related deaths, and approximately $50 billion in medical costs. This resulted in a total cost of asthma in the United States of approximately $82 billion in 2013 according to the American Thoracic Society.

In 2016, of the approximately 19 million asthma patients over 12 years of age in the United States, about 41%, or 7.8 million, had moderate-to-severe asthma; of the approximately 47.8 million asthma patients over 12 years of age in Europe, about 45%, or 21.5 million, had moderate-to-severe asthma. About 40% of moderate-to-severe asthma patients have uncontrolled asthma, which amounts to approximately 3.1 million patients with moderate-to-severe uncontrolled asthma in the United States and approximately 8.6 million in Europe according to an analysis prepared by Artisan Healthcare Consulting. There are several biologics approved for moderate-to-severe uncontrolled asthma in the United States and Europe. Omalizumab is an anti-IgE monoclonal antibody marketed by Roche/Genentech for moderate-to-severe persistent allergic asthma and chronic idiopathic urticaria; in 2018, Roche/Genentech reported total global sales for omalizumab in the amount of CHF 1,912 million ($1,905 million). Mepolizumab is an anti-IL5 monoclonal antibody marketed by GlaxoSmithKline, or GSK, for severe eosinophilic asthma; in 2018, GSK reported global sales for mepolizumab in the amount of £563 million ($727 million). Benralizumab is an anti-IL5 receptor monoclonal antibody marketed by AstraZeneca for severe eosinophilic asthma; in 2018 AstraZeneca reported global sales for benralizumab in the amount of $297 million. Dupilumab is an anti-IL4Rα monoclonal antibody marketed by Sanofi/Regeneron for atopic dermatitis and moderate-to-severe uncontrolled asthma; in 2018, Sanofi/Regeneron reported total global sales of dupilumab in the amount of $922 million.

Challenges in using conventional therapy

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 uncontrolled moderate-to-severe allergic asthma, omalizumab is sometimes 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, which 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 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.

Beyond omalizumab, there are four approved biologics for the treatment of asthma. Three target the IL-5 pathway and one targets IL-4Rα. GSK's mepolizumab, which targets IL-5, was approved for severe eosinophilic asthma in adults and children older than 12 in 2015. Teva's reslizumab, also targeting IL-5, was approved in 2016 and AstraZeneca’s benralizumab, which targets IL-5 receptor alpha, or IL-5Rα, was approved in November 2017.

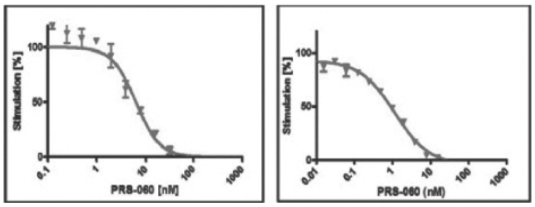
Dupilumab is an antibody that targets IL-4Rα that is delivered subcutaneously and was approved for the treatment of moderate-to-severe atopic dermatitis in March 2017. In October 2018, Regeneron and its partner Sanofi announced that the FDA had approved dupilumab as "add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma." In the phase 3 Liberty Asthma Quest study, dupilumab (300 mg every 2 weeks) in the pre-specified high eosinophilic group (eosinophil blood count of ≥ 300 cells/microliter) demonstrated a reduction in annualized rate of severe exacerbations by 67.4% and an improvement in forced expiratory volume in one second, or FEV1, by 0.24L. The Liberty Asthma Venture trial evaluated dupilumab in oral glucocorticoid-dependent severe asthma patients. In the overall population, the percentage of patients that decreased oral corticosteroid use by 50% or more was 80% in the dupilumab group versus 50% for placebo (or a 60% relative reduction), while decreasing the rate of severe exacerbations by 59% and improving FEV1 by 0.22L versus placebo. In the high eosinophilic group, dupilumab decreased the rate of severe exacerbations by 71% and improved FEV1 by 0.32L versus placebo (Rabe et al., 2018).

Advantages to inhalation as a route of administration for PRS-060/AZD1402

We believe that local delivery via inhalation may lead to a better tolerability profile than systemically administered antibodies. Since dosing by inhalation is a common route of administration in asthma patients, it could represent a more convenient dosage regimen for patients than dosing of antibodies by injection. PRS-060/AZD1402 was safe and well-tolerated in a SAD phase 1 study, and the drug candidate is currently being evaluated in a MAD phase 1 study with interim data suggesting that PRS-060/AZD1402 was safe and well tolerated at all doses, led to a statistically significant reduction in FeNO and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO.

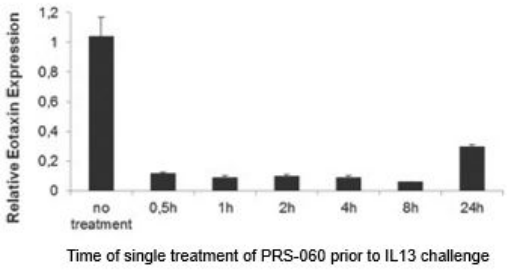
Preclinical data

In *in vitro* assays, PRS-060/AZD1402 specifically bound to immobilized targets such as human IL-4Rα in a concentration-dependent manner. We tested the binding of PRS-060/AZD1402 to various targets in an enzyme-linked immunosorbent assay, or ELISA, a standard *in vitro* assay platform. In these tests, PRS-060/AZD1402 bound to IL-4Rα with subnanomolar affinity and it did not bind to three other human cell-surface interleukin receptors (IL-6R, IL-18Rα, IL-23Rα). Furthermore, the activity of IL-4 and IL-13 was inhibited by PRS-060/AZD1402 in a dose-dependent manner. The 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/AZD1402.

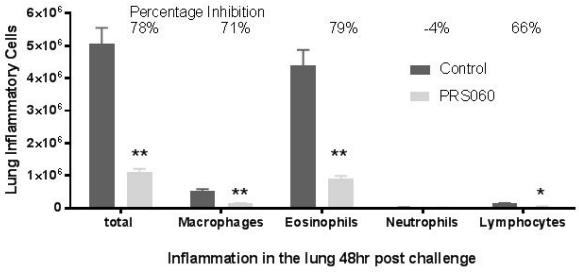


In *in vivo* assays in mice genetically altered to express human IL-4Rα, human IL-4 and IL-13, low doses of lung delivered PRS-060/AZD1402 inhibited the induction of eotaxin protein, a marker of airway inflammation, in lung tissue following pulmonary delivery. We observed this inhibition at both the RNA and protein levels compared both to buffer and to tear lipocalin (control).

The chart below shows the duration of PRS-060/AZD1402-mediated inhibition of eotaxin gene expression in lung tissue by a single pulmonary dose in mice:



When we administered IL-13 into the lung of humanized mice (that express human IL-4, IL-13 and IL-4Rα), 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 or wild-type lipocalin administration, increases in eotaxin expression were prevented when PRS-060/AZD1402 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/AZD1402 administration. We have also demonstrated that PRS-060/AZD1402 reduces the inflammation associated with antigen challenge in a mouse asthma model. The chart below shows that pre-treatment with PRS-060/AZD1402 reduces the lung levels of the key inflammatory cells' eosinophils and lymphocytes, a profile that supports the hypothesis that lung delivery of an IL-4Rα antagonist to asthmatics may be viable approach to the treatment of asthma.



Clinical data

PRS-060/AZD1402 was tested in a nebulized formulation in 54 healthy volunteers at nominal dose levels ranging from 0.25 mg to 400 mg in a phase 1 SAD study; the drug candidate was safe and well-tolerated in the volunteers in that study. Data from that study were presented at the American Thoracic Society International Conference in May 2019 showing that PRS-060/AZD1402 was well tolerated when given as a single inhaled or intravenous doses to healthy volunteers and there was systemic target engagement (as measured by pSTAT6 inhibition). We presented interim data from the PRS060/AZD1402 phase 1 MAD study at the 2019 European Respiratory Society International Congress in October 2019 and reported that PRS-060/AZD1402 was safe and well tolerated at all doses, led to a statistically-significant reduction in FeNO, a validated biomarker for eosinophilic airway inflammation, and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO (≥ 35ppb). During the treatment period, 30 patients were randomized to receive delivered doses of PRS-060/AZD1402 ranging from 2 mg to 60 mg (5 mg to 150 mg administered through a nebulizer (nominal dose)) twice daily for nine consecutive days and one final dose on the 10th day, and 12 patients were randomized to receive placebo at the same intervals. Statistically significant and pronounced inhibition of FeNO relative to placebo was observed at all doses. When comparing the 20 mg PRS-060/AZD1402 powered cohort (n=12) to placebo, the primary statistical analysis using the emax model demonstrated a 36% relative reduction in FeNO (p-value <0.0001). Systemic target engagement was dose-dependent and closely aligned with systemic exposure of the drug, consistent with results of the phase 1 SAD study. Minimal systemic exposure and target engagement were observed at the 2 mg dose, suggesting that local target engagement by the drug may be sufficient to reduce airway inflammation, as evidenced by FeNO reduction at that 2 mg dose level. Following these reported results, AstraZeneca and Pieris are preparing to initiate a phase 2a study in moderate-to-severe asthmatics in the second half of this year.

Proprietary Respiratory Platform

We continue to advance several proprietary discovery-stage respiratory programs. We expect to share data and rationale for advancement of one of our proprietary respiratory programs at a medical meeting in the second half of this year.

AstraZeneca Respiratory Collaboration Beyond PRS-060/AZD1402

As further described below, our license and collaboration agreement with AstraZeneca, or the AstraZeneca Collaboration Agreement, includes four programs beyond PRS-060/AZD1402. We retain co-development and co-commercialization rights to two out of those four programs. We have initiated discovery work on the three additional development candidates under the collaboration. The targets and disease areas of those three programs are undisclosed. AstraZeneca will have the option to initiate the fourth discovery program in the collaboration this year.

PRS-343 Targeting 4-1BB (CD-137) in Oncology

PRS-343 is a bispecific protein targeting the immune receptor 4-1BB and the tumor target HER2. It is generated by genetic fusion of an Anticalin protein specific for 4-1BB to each heavy chain of a variant of a HER2-targeting antibody. The mode of action of this 4-1BB/HER2 bispecific is to promote 4-1BB clustering by bridging 4-1BB-positive T-cells with HER2-positive tumor cells, and to thereby provide a potent co-stimulatory signal to tumor antigen-specific T-cells. PRS-343 is intended to localize 4-1BB activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to 4-1BB-targeting antibodies being developed by third parties in clinical trials. We initiated a phase 1 dose-escalation study of PRS-343 in HER2 positive patients in September 2017 and a phase 1 dose-escalation study of PRS-343 in combination with atezolizumab in HER2 positive patients in August 2018. We presented interim data from the study at the SITC annual meeting on November 9, 2019. We reported that PRS-343 was well tolerated and had a favorable safety profile at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types and showed a potent increase in CD8+ T-cell numbers in the tumor microenvironment of responders, indicative of 4-1BB agonism on T-cells. We continue to enroll patients in that study at higher dose cohorts and modified dosing schedules and plan to initiate a further trial of the drug candidate in gastric cancer this year based on continued encouraging results from the trial. We also plan to conclude and report complete data from the dose escalation study of PRS-343 in combination with atezolizumab this year.

Biology of the co-stimulatory immune receptor 4-1BB

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. 4-1BB plays an important role in the regulation of immune responses and thus is a target for cancer immunotherapy. 4-1BB ligand, or 4-1BBL, is the only known natural ligand of 4-1BB and is constitutively expressed on several types of antigen-presenting cells, or APC. 4-1BB-positive T-cells are activated by engaging a 4-1BBL-positive cell. The induced 4-1BB clustering leads to activation of the receptor and downstream signaling. In a T-cell pre-stimulated by the T-cell receptor, or TCR, binding to a cognate major

histocompatibility complex, or MHC, target, co-stimulation via 4-1BB 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 4-1BB as a therapeutic target in cancer

The benefit of 4-1BB co-stimulation for the elimination of cancerous tumors has been demonstrated in a number of murine in vivo models. The forced expression of 4-1BBL on a tumor, for example, leads to tumor rejection. Likewise, the forced expression of an anti-4-1BB single chain antibody fragment, or scFv, on a tumor leads to a CD4+ T-cell and NK-cell dependent elimination of the tumor. A systemically administered anti-4-1BB antibody has also been demonstrated to lead to retardation of tumor growth.

Human *ex vivo* data support the potential of 4-1BB as a co-stimulatory receptor in cancer therapy. It has been reported that for T-cells isolated from human tumors, 4-1BB is an effective marker for those that are tumor-reactive. Based on this observation, we believe that 4-1BB targeting can be utilized to improve adoptive T-cell therapy, or ACT, by augmenting the expansion and activity of CD8+ melanoma tumor-infiltrating lymphocytes, or TILs.

Finally, the potential of 4-1BB targeting has also been shown in nonclinical combination therapy studies, where an additional benefit was demonstrated by combination of 4-1BB agonism with checkpoint blockade or NK cell-targeting antibodies.

Current approaches to clinical 4-1BB targeting

The demonstration of the potential therapeutic benefit of 4-1BB co-stimulation in nonclinical models has spurred the development of therapeutic antibodies targeting 4-1BB, utomilumab and urelumab.

Utomilumab is a humanized IgG2 antibody that binds 4-1BB in a manner that blocks the binding of endogenous 4-1BBL to 4-1BB, and that according to publicly available data is well tolerated as a monotherapy and in combination with rituximab.

Urelumab is an IgG4 antibody that, in contrast to utomilumab, binds 4-1BB in a manner that does not interfere with the 4-1BB / 4-1BBL interaction. While an initial study reported manageable toxicity with doses up to 10 mg/kg, a follow-up monotherapy phase 2 study was reported to have been stopped due to an “unusually high incidence of grade 4 hepatitis.” Prior clinical trials with urelumab were focused on safety and efficacy at lower doses as monotherapy or in combination, for example, with rituximab (NCT01775631).

Rationale for bispecific targeting of 4-1BB

We believe that the natural mode of activation of 4-1BB, which requires receptor clustering, demonstrates that an ideal 4-1BB-targeting agent should firstly lead to clustering of 4-1BB, and secondly do so in a tumor-localized fashion on TILs. The antibodies currently in clinical development are not ideal in that respect, as 4-1BB clustering can only be induced by binding to Fcg receptor-positive cells, which are not selectively tumor-localized but distributed throughout the body for Fcg-dependence of TNFR targeting. The toxicity data of urelumab indicates that such a non-selective activation leads to unacceptable toxicity, potentially making it impossible to find a therapeutic window for such 4-1BB-targeting antibodies.

We therefore hypothesized that to obtain an ideal 4-1BB-targeting agent, a bispecific molecule should be designed that targets 4-1BB 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. HER2/4-1BB bispecific is envisioned to promote 4-1BB clustering by bridging T-cells with HER2-positive tumor cells, and to thereby provide a potent co-stimulatory signal to tumor antigen-specific T-cells, further enhancing its TCR-mediated activity and leading to tumor destruction.

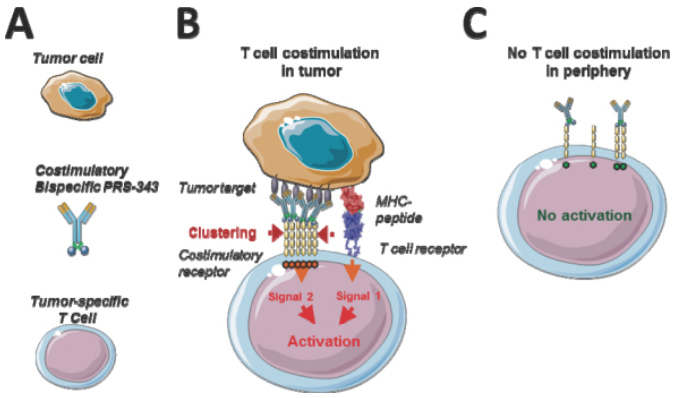


Figure 1 Concept of co-stimulatory T-cell engagement. (A) The elements of the system are a target-positive tumor cell, a T-cell with a TCR that is specific for an HLA/peptide combination on the tumor, and a co-stimulatory bispecific. (B) Within a patient´s tumor, tumor-specific T-cells are bridged with tumor cells by a co-stimulatory bispecific. The resulting clustering of the co-stimulatory TCR 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 co-stimulation 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 HER2/4-1BB bispecific PRS-343.

To obtain a molecule that would work by the mode of action of co-stimulatory T-cell engagement, we generated the HER2/4-1BB bispecific PRS-343. The molecule consists of two different building blocks binding to the two targets HER2 and 4-1BB. To generate the 4-1BB-specific building block of PRS-343, we utilized Anticalin technology. A 4-1BB-binding Anticalin protein 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 resulting 4-1BB targeting Anticalin protein binds human 4-1BB with an affinity of 2 nM as determined by surface plasmon resonance, or SPR, and is capable of co-stimulating human T-cells when immobilized on a plastic dish together with an anti-CD3 antibody.

To generate the bivalent HER2/4-1BB bispecific PRS-343, we constructed a genetic fusion of a 4-1BB-specific Anticalin protein to the C-terminus of each heavy chain of a HER2-binding antibody, connected by a flexible, non-immunogenic linker.

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. The 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 co-stimulatory engagement of T-cells by HER2-positive target cells.

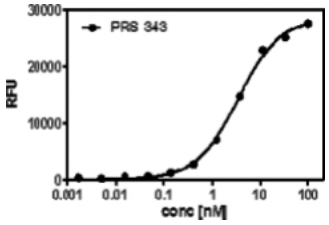


Figure 2 PRS-343 simultaneous binding to targets HER2 and 4-1BB. Recombinant Her2 was coated on a microtiter plate, followed by titration of PRS-343. Subsequently, a constant concentration of biotinylated human 4-1BB was added, which was detected via a peroxidase-conjugated avidin variant.

Mode of action – co-stimulatory T-cell activation

We developed a novel T-cell activation assay format to investigate whether PRS-343 is capable of co-stimulating T-cells that have received a basic stimulus via the TCR. The assay, visualized in Figure 3 below, is based upon providing the TCR stimulus via an anti-CD3 antibody coated onto the plastic culture dish, while 4-1BB co-stimulation is achieved by tumor-target dependent clustering of 4-1BB on purified T-cells.

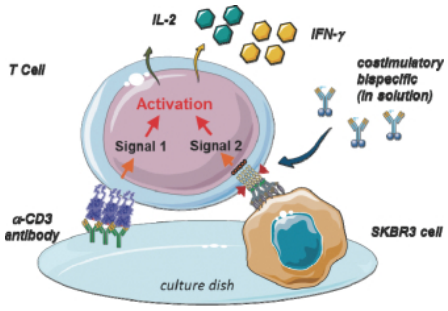


Figure 3 Visualization of co-stimulatory T-cell activation assay. HER2-positive tumor cells are grown overnight on cell culture plates that have been precoated with low amounts of an anti-CD3 antibody to provide a limited primary activation of T-cells via the T-cell receptor. T-cells are added to the wells together with the titrated 4-1BB/HER2 bispecific PRS-343, leading to clustering of the co-stimulatory 4-1BB receptor, which in turn results in T-cell co-stimulation. T-cell co-stimulation 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 4A) and IFN-γ (Figure 4C) 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-α induction, respectively. That T-cell co-stimulation is indeed, due to the bispecific engagement of T-cells and SKBR3 cells, shown by two observations: firstly, the monospecific HER2-targeting antibody 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 HER2-targeting antibody abolishes the effect of IL-2 and INF-γ induction almost completely, except at the highest concentrations of PRS-343 employed (Figure 4B and Figure 4D).

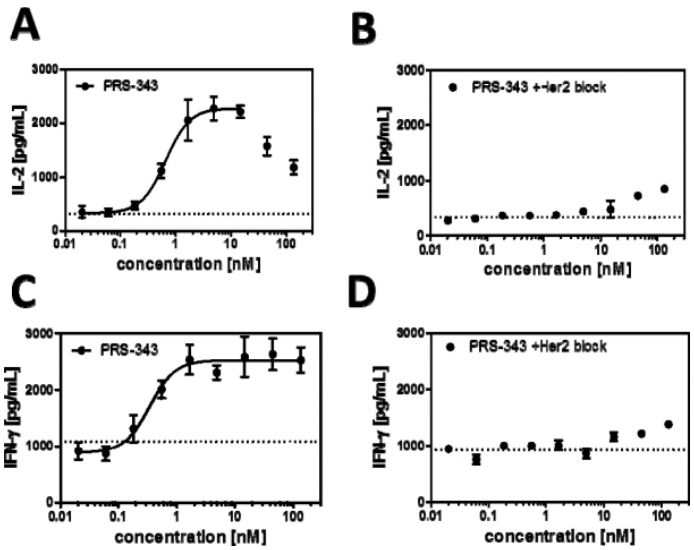
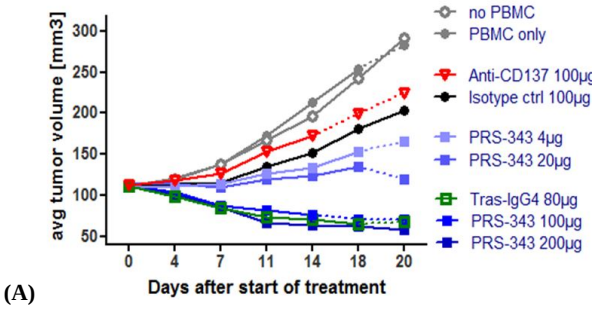
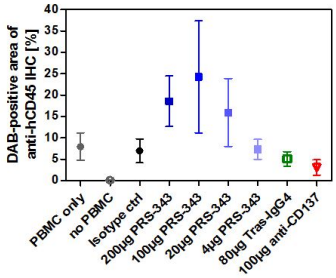


Figure 4 Experimental result of co-stimulatory T-cell activation assay. HER2-positive tumor cells were grown overnight on 96-well plates that had been precoated with 0.25 µg/mL anti-CD3 antibody for 1 hour at 37°C. The next day, T-cells purified from healthy donor peripheral blood mononuclear cells,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

Proof of concept data utilizing a humanized SK-OV-3 mouse model demonstrated dose-dependent tumor growth inhibition compared to treatment with the isotype control (Figure 5). It is anticipated that the tumor growth inhibition, or TGI, in this model is predominantly caused by the anti-HER2 activity. The anti-tumor response observed with PRS-343 was accompanied by a significantly higher tumor infiltration with human lymphocytes (hCD45+). Interestingly, the anti-4-1BB benchmark neither displayed tumor growth inhibition nor enhanced lymphocyte infiltration into tumors compared to isotype. The tras-IgG4 control was also devoid of lymphocyte infiltration into the tumor but displayed a tumor growth inhibition comparable to PRS-343. Taken together, these data show that PRS-343 provided dual activity by both increasing the frequency of TILs by bispecific targeting of CD137 and HER2 as well as mediating direct tumor growth inhibition by the direct, monospecific targeting of HER2.



(A)



(B)

Figure 5 PRS-343 activity in mice engrafted with HER2-positive SK-OV-3 cell line and human PBMC. (A) Median of tumor growth. (B) Frequency of CD45+ cells determined by immunohistochemistry of tumors after study end.

Clinical data

We presented interim data from our phase 1 escalation study of PRS-343 at the SITC annual meeting on November 9, 2019. We disclosed that PRS-343 was well tolerated and had a favorable safety profile at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types and showed a potent increase in CD8+ T-cell numbers in the tumor microenvironment of responders, indicative of 4-1BB agonism on T-cells. We continue to enroll patients in that study at higher dose cohorts and modified dosing schedules and plan to initiate a further trial of the drug candidate in gastric cancer this year. We also plan to conclude and report complete data from the dose escalation study of PRS-343 in combination with atezolizumab in 2020.

PRS-344

PRS-344 consists of a PD-L1-targeting antibody and 4-1BB-targeting Anticalin proteins genetically fused to each arm of the C-terminal heavy chain of the antibody.

4-1BB is a co-stimulatory receptor belonging to the TNFR super-family. Clustering of 4-1BB on the surface of T-cells leads to T-cell activation, proliferation and cytokine secretion. The mode of action of PRS-344 is to promote 4-1BB clustering by bridging 4-1BB-positive T-cells with PD-L1-positive tumor cells, and to thereby provide a potent co-stimulatory signal to tumor antigen-specific T-cells. PRS-344 is intended to localize 4-1BB activation in the tumor in a PD-L1 dependent manner. PD-L1 is a transmembrane protein belonging to the B7 family and is expressed on a variety of cells including T-cells, B cells, epithelial and vascular endothelial cells. Most importantly, PD-L1 is found at high levels on tumor cells of several cancer types including but not limited to melanoma, lung, bladder, colon, and breast cancer. Binding of PD-L1 to its receptor PD-1 leads to exhaustion of tumor-infiltrating T-cells. PRS-344 blocks the PD-1/PD-L1 interaction and thus is capable of reversing T-cell exhaustion in the tumor microenvironment. Preclinical data shows that the synergistic effect observed by targeting PD-L1 and 4-1BB simultaneously is stronger with PRS-344 than with the combination of anti-PD-L1 and anti-4-1BB antibodies.

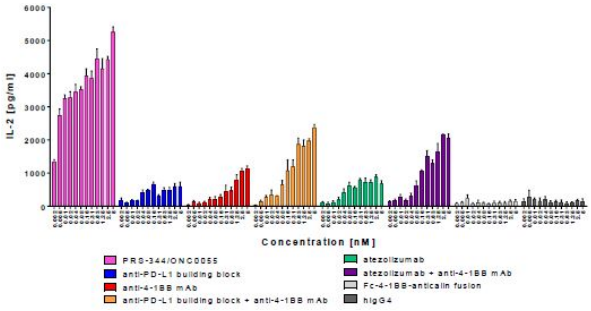


Figure 1 The combination of anti-PD-L1 benchmark and anti-4-1BB benchmark demonstrates the strong synergistic effect of T-cell co-stimulation and checkpoint blockade in T-cell activation. With PRS-344, this synergistic effect is massively increased.

Together with our partner Servier, we plan to file an IND for the program in the first half of 2020. This first-in-human study will consist of evaluating the safety and tolerability profile of PRS-344 and determining its maximum tolerated dose, or MTD, and/or the recommended phase 2 dose, or RP2D, in patients with solid tumors. In addition, the PK profile as well as pharmacodynamic effects of the PRS-344 will be characterized in the study. Any initial signs of anti-tumoral activity will be correlated to safety and PK and further explored in expansion cohorts.

IO Market with respect to PRS-343 and PRS-344

In 2019 there were approximately 1.762 million estimated new cancer cases in the United States (NCI Surveillance, Epidemiology, and End Results Program) and approximately 18.1 million cancer cases worldwide (IARC GLOBOCAN 2018). The direct medical cost for cancer in the United States in 2015 was estimated to be approximately $80.2 billion by the Agency for Healthcare research and Quality, or the AHRQ.

Checkpoint inhibitors such as PD-1 and CTLA4-targeting antibodies have revolutionized the way certain cancers are treated and in 2018 the Noble Prize in Medicine was awarded to Dr. James Allison and Dr. Tasuku Honjo for their discovery of CTLA-4 and PD-1-targeting antibodies, respectively. By the end of 2018 a total of six anti-PD-1 or PD-L1 monoclonal antibodies and one CTLA4 targeting antibody have been approved in the United States. Global sales in 2018 for these seven checkpoint inhibitors exceeded $16 billion. In addition, other than the six anti-PD-1 or PD-L1 monoclonal antibodies approved in the Unites States, four other anti-PD-1 monoclonal antibodies had been approved in China by the end of 2019. The majority of the global sales of checkpoint inhibitors comes from two anti-PD-1 monoclonal antibodies: pembrolizumab marketed by Merck & Co and nivolumab marketed by Bristol-Myers Squibb. In 2018, Merck & Co reported sales of $7.171 billion for pembrolizumab and Bristol-Myers Squibb reported sales of $6.735 billion for nivolumab.

Other IO Programs

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. Our IO pipeline beyond PRS-343 and PRS-344 is designed to target checkpoint proteins or, like PRS-343, co-stimulatory proteins. These programs consist of a variety of multifunctional biotherapeutics that can encompass a fusion of antibodies with Anticalin proteins or two or more Anticalin proteins to each other. These combined molecules have the potential to build upon current therapies by 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 or co-stimulatory targets can preferentially activate the immune system at the site of the tumor microenvironment thus providing efficacy with enhanced therapeutic index. We believe that these bispecific constructs represent a “platform within a product” opportunity in IO since it may be possible to apply a single combined Anticalin-antibody molecule in a number of different cancers. This belief is based on the shared underlying biology such as checkpoint and co-stimulatory biology found within tumors arising in different organs.

Servier Collaboration Beyond PRS-344

As further described below, our Servier Collaboration Agreement includes three active programs beyond PRS-344. We retain co-development and co-commercialization rights to two programs, including PRS-344. These additional programs have been defined, and may combine antibodies with one or more Anticalin proteins based on our proprietary platform to generate innovative immuno-oncology bispecific drug candidates. In September 2019, Servier decided to discontinue co-development of PRS-332, but we retain full rights to advance the development and commercialization of the drug candidate on a world-wide basis. Servier's decision to discontinue PRS-332 does not impact the rest of the Servier Collaboration Agreement.

In addition, effective in January of this year, Servier and Pieris agreed to extend the research term of the three programs in development beyond PRS-344 for one year. This research extension includes reimbursement for Pieris’ internal efforts and an extension of the research license.

Seattle Genetics Collaboration

In addition, our collaboration with Seattle Genetics to discover and develop Anticalin-based tumor-targeted bispecific therapeutics in IO includes up to three programs. We retain a co-development and co-commercialization option for one of these three programs.

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 worldwide.

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, have more institutional experience, and greater cash flows than us, 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 respiratory diseases and cancer, 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 drugs in clinical development to treat respiratory diseases and 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;

- performing preclinical and clinical trials of potential pharmaceutical products; and
- obtaining regulatory approval.

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

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

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-060/AZD1402

Like PRS-060/AZD1402, new developments for the treatment of uncontrolled moderate to severe asthma patients mainly include drug candidates targeting the Th2 pathway by interfering with IL-4/IL-13, IL-5, IL-33, TSLP or CRTH2. Such agents include mepolizumab (GSK, IL-5), reslizumab (Teva, IL-5), benralizumab (AstraZeneca, IL-5Rα), tezepelumab (Amgen/AstraZeneca, TSLP), etokimab (AnaptysBio, IL-33) and REGN-3500/SAR-440340 (Regeneron/Sanofi, IL-33). These drugs are in later clinical development than PRS-060/AZD1402 (tezepelumab, etokimab and REGN-3500/SAR-440340), or have been approved (mepolizumab, reslizumab, benralizumab) for severe eosinophilic asthma. Dupilumab (Sanofi/Regeneron, IL-4Rα) has been approved for severe to moderate asthma; the antibody omalizumab, directed against IgE, is also approved and marketed for the treatment of uncontrolled, moderate to severe asthma patients. However, in contrast to PRS-060/AZD1402, these antibodies are given to patients through injection and distribute systemically through the blood stream. CSJ117 (Novartis), an inhaled Fab fragment that targets TSLP, is currently in phase 1 clinical development. There are a number of other companies presently marketing or developing other therapies for asthmatic patients.

IO programs

The rationale behind the multispecific tumor-targeted co-stimulatory molecules is to activate the immune system in the tumor microenvironment. Other companies that also develop multispecific drug candidates designed to activate the immune system in a tumor dependent manner by targeting a co-stimulatory receptor, such as 4-1BB, include Roche, Molecular Partners, Alligator Biosciences, Aptevo Therapeutics and Genmab, among others. Additionally, there are multiple drug candidates in preclinical or clinical trials targeting other co-stimulatory receptors, either in a tumor dependent or monospecific manner, including OX40, CD40, GITR, CD27 and ICOS.

The first checkpoint inhibitor, ipilimumab, targeting CTLA-4 was approved for the treatment of melanoma patients in 2011 and is being marketed by Bristol-Myers Squibb. Nivolumab from Bristol-Myers Squibb was approved for the treatment of melanoma in 2014 as the first PD-1 inhibitor. Pembrolizumab from Merck & Co was the second PD-1 inhibitor to be approved and the first one in the United States. In addition to nivolumab and pembrolizumab there are multiple approved checkpoint inhibitors targeting the PD-1/PD-L1 pathway, for example, those from Roche, AstraZeneca, Pfizer, and Merck KGaA.

There are also drug candidates in preclinical or clinical testing for other checkpoint targets such as LAG3, TIM3 and B7-H3. Companies developing either dual-checkpoint inhibitors or combinations of two or more monospecific checkpoint inhibitors includes Xencor, F-Star, Bristol-Myers Squibb, Merus, GSK, Novartis, Merck & Co. among others.

Additionally, a number of other companies, such as Amgen, Affimed, Macrogenics, F-Star, Molecular Partners, Xencor, Immunocore and Zymeworks, also pursue other multispecific approaches in oncology, in which such therapies are in clinical or preclinical development.

PRS-343

PRS-343 is bispecific Anticalin-antibody fusion protein targeting 4-1BB and HER2. PRS-343 has a bifunctional proposed mode of action. It is designed to both promote 4-1BB clustering by bridging 4-1BB-positive T-cells with HER2-positive tumor cells, and to thereby provide a co-stimulatory signal to tumor antigen-specific T-cells and inhibit HER2 signaling. Other drug candidates targeting the co-stimulatory receptor 4-1BB include urelumab, which is being developed by Bristol-Myers Squibb, and utomilumab, which is being developed by Pfizer, both of which are currently in clinical development (Trialtrove, January 18, 2020). 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. In addition to PRS-343, there are also other HER2 targeting drug candidates in clinical development designed to induce an immune response by bridging HER2-positive tumor cell with immune cells, for example, GBR 1302, a bispecific antibody targeting HER2 and CD3, from Glenmark (Pharmaprojects, December 6, 2018).

Further trials with PRS-343 are being planned in gastric cancer this year. Trastuzumab in combination with cisplatin and 5-FU or capecitabine is currently standard of care for 1st line HER2+ metastatic gastric or GEJ adenocarcinoma. Other drug candidates or novel combinations being developed in HER2+ cancer include pembrolizumab in combination with trastuzumab and chemotherapy (Merck & Co, KEYNOTE-811), trastuzumab deruxtecan (Daiichi Sankyo/AstraZeneca, DESTINY-Gastric01), margetuximab in combination with a checkpoint inhibitor, with or without chemotherapy (MacroGenics, MAHOGANY) and ZW25 (Zymeworks) among others. There are also other non-HER2 targeted drug candidates or combinations being developed more broadly, which may or may not overlap with drug candidates being developed in a HER2+ patient population.

One company has publicly disclosed a competitor HER2 and 4-1BB bispecific program. MacroGenics presented data on a HER2 and 4-1BB bispecific during their R&D day on December 13th, 2016. In addition to MacroGenics, other companies have also disclosed 4-1BB-based bispecific drug candidates. Roche and Molecular Partners have both presented data on bispecific drug candidates targeting fibroblast activation protein, or FAP, and 4-1BB. Alligator Bioscience together with Aptevo Therapeutics have disclosed a 4-1BB-based bispecific drug candidate targeting 5T4. However, the 4-1BB-based bispecific drug candidates targeting FAP or 5T4 do not constitute direct competition to PRS-343 since they are targeting a different tumor target and will, thus, likely be developed in different indications or patient populations.

PRS-344

PRS-344 is bispecific Anticalin-antibody fusion protein targeting 4-1BB and PD-L1. PRS-344 is, similar to PRS-343, designed to promote 4-1BB clustering by bridging 4-1BB-positive T-cells with, in the case of PRS-344, PD-L1-positive tumor cells, and to thereby provide a co-stimulatory signal to tumor antigen-specific T-cells. Furthermore, the direct PD-L1- targeting activity of PRS-344 may provide an additional therapeutic benefit by checkpoint blockade. Multiple companies have publicly disclosed competing 4-1BB and PD-L1 bispecific programs, including, for example, Genmab in collaboration with BioNTech (GEN1046), Incyte in collaboration with Merus(MCLA-145), Inhibrx in collaboration with Elpiscience (INBRX-105), F-Star (FS-222), MacroGenics, and Numab in collaboration with CStone. GEN1046, MCLA-145 and INBRX-105 are currently in phase 1 clinical development.

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 manufacturer organizations, 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 drug substances and finished drug products, and label and packaging for our preclinical research and clinical trials, including the phase 1 study for PRS-060/AZD1402, the phase 1 studies for PRS-343 and the planned phase 1 study for PRS-344.

We believe that we will be able to contract with other CMOs to obtain drug substances if our existing sources of drug substances were no longer available or sufficient, but there is no assurance that the drug substances would be available from

other CMOs on acceptable terms, on the timeframe that our business would require, or at all. We do not have 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 CMO 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 cGMP 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 CMOs.

We believe that PRS-060/AZD1402, PRS-343 and PRS-344 and our other Anticalin-branded drug candidates can be manufactured in reliable and reproducible biologic processes from readily available starting materials. PRS-060/AZD1402 is produced using a bacterial expression system 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 and PRS-344 are produced using mammalian expression systems similar to those systems that 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 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 trade secrets, 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 have established intellectual property protection in relation to our Anticalin technologies in key global markets, including in North America, Europe and Asia. We also rely on trade secrets for confidential know-how, which we generally seek to protect through contractual (for example, 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 the Pieris and Anticalin marks 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 the use of any of our drug candidates, or with respect to pharmaceutical formulations that may be useful to produce final medicinal products.

We own, or are the exclusive licensee, of a patent portfolio consisting of several issued U.S. patents, and their respective counterparts in a number of foreign jurisdictions, including pending patent applications under the Patent Cooperation Treaty, pending U.S. patent applications and corresponding pending patent applications in a number of foreign jurisdictions as well as pending provisional patent applications, as described in further detail below.

In applicable jurisdictions, we will seek patent term extensions for certain issued 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 certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as 12 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, eight to 11 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.”

We hold issued patents and pending patent applications in the United States and other foreign jurisdictions, which patents are related to libraries of different scaffolds and consensus sequences such as human apolipoprotein D, human NGAL, 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 a number of patents and patent applications at various stages of prosecution directed towards compositions of mater and in some cases, formulations or methods of use, of our preclinical and clinical drug candidates. Where possible, we will pursue patent term adjustments in the United States and any applicable foreign jurisdictions.

As a result of our research and licensing agreement, or the TUM License, with Technische Universität München, or TUM, we hold a worldwide exclusive license to multiple issued patents and pending patent applications. These patents and patent applications relate to Anticalin proteins derived from hNGAL lipocalin muteins and/or a library of an hNGAL scaffold of a certain consensus sequence, which patent is expected to expire in 2029, subject to any patent term adjustments or terminal disclaimers in the United States. We also hold an exclusive license to issued patents or pending patent applications related to bacterial lipocalin muteins and a1m lipocalin muteins.

We hold a number of issued patents and pending patent applications in the United States and foreign jurisdictions directed to newly-discovered or improved scaffold libraries of lipocalin muteins, compounds derived therefrom (i.e., specific drug candidates), 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 these patents and any patents that may issue from pending applications would likely expire between 2029 and 2040 without taking into account possible patent term adjustments or other extensions, however, any and all of these pending patent applications may not result in issued patents, and not all issued patents may be maintained in force for their entire term. We are actively pursuing intellectual property protection for our IO drug candidates in key global markets that, if granted, could expire as late as 2040 or later depending on the date of the filing of such patent applications.

In addition to issued patents, we hold trademarks in the United States for the Pieris and Anticalin marks. 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 and Other License Agreements

Since 2007, we have entered into several strategic partnerships and other license or option agreements to complement our drug discovery and development. Specifically, we have entered into strategic partnerships with Servier, AstraZeneca and Seattle Genetics, or collectively, the Strategic Partnerships, and other non-strategic license agreements or collectively, the License Agreements. Under the Strategic Partnerships and License Agreements, 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 libraries, and other proprietary methods to generate, identify, and characterize drug candidates against certain biological targets associated with several diseases. The Strategic Partnerships have provided us with approximately $122.1 million in cash from upfront and milestone payments to date. With respect to discontinued agreements, we have no ongoing performance obligations, and do not expect to receive any significant additional consideration pursuant to those agreements.

Under our ongoing Strategic Partnerships and License Agreements, 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 some cases, including in the Servier, AstraZeneca and Seattle Genetics collaborations, royalties on net sales for products developed and commercialized under these collaborations. With respect to our Strategic Partnerships, we have commercial rights, including the option to co-develop or co-commercialize one or more therapeutic programs with the applicable partners. We plan to continue to actively seek out additional collaboration partners that fit within our corporate development strategy.

The Strategic Partnerships represent our cornerstone collaborations in our key therapeutic areas of respiratory diseases and IO and include co-development and co-commercialization options. Certain terms and conditions of these Strategic Partnerships are summarized below.

Our collaboration with AstraZeneca

On May 2, 2017, we entered into the AstraZeneca Collaboration Agreement and a non-exclusive Anticalin platform technology license agreement with AstraZeneca, or the AstraZeneca Platform License, collectively referred to as the AstraZeneca Agreements, which became effective on June 10, 2017, following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Under the AstraZeneca Agreements the parties will advance several novel inhaled Anticalin proteins.

Under the AstraZeneca Agreements, we received an upfront, non-refundable payment of $45.0 million. In addition, we initiated a phase 1 study for the PRS-060, or the AstraZeneca Lead Product, or AZD1402, in December 2017 for which we received a $12.5 million milestone payment. We are also eligible to receive research, development, commercial, and sales milestone payments and royalty payments. The total potential milestones are categorized as follows: research, development, and commercial milestones up to $1.1 billion; and sales milestones up to $1.0 billion. We may receive tiered royalties on sales of potential products commercialized by AstraZeneca and for co-developed products, gross margin share of worldwide sales, depending on our level of committed investment.

The term of each of the AstraZeneca Agreements ends upon the expiration of all of AstraZeneca's payment obligations under such AstraZeneca Agreement. The AstraZeneca Collaboration Agreement may be terminated by AstraZeneca in its entirety for convenience beginning 12 months after its effective date upon 90 days' notice or, if we have obtained marketing approval for the marketing and sale of a product, upon 180 days' notice. Each program may be terminated at AstraZeneca's option; if any program is terminated by AstraZeneca, we will have full rights to such program. The AstraZeneca Collaboration Agreement may also be terminated by AstraZeneca or us for material breach upon 180 days' notice of a material breach (or 30 days with respect to payment breach), provided that the applicable party has not cured such breach by the permitted cure period (including an additional 180 days if the breach is not susceptible to cure during the initial 180-day period) and dispute resolution procedures specified in the applicable AstraZeneca Agreement have been followed. Each party may also terminate an AstraZeneca Agreement if the other party challenges the validity of patents related to certain intellectual property licensed under such AstraZeneca Agreement, subject to certain exceptions for infringement suits, acquisitions and newly-acquired licenses. The AstraZeneca Collaboration Agreement may also be terminated due to the other party's insolvency and may in certain instances be terminated on a product-by-product and/or country-by-country basis. The AstraZeneca Platform License will terminate upon termination of the AstraZeneca Collaboration Agreement, on a product-by-product and/or country-by-country basis.

Our collaboration with Servier

On January 4, 2017, we entered into the Servier Collaboration Agreement and a non-exclusive Anticalin platform license agreement with Servier, or the Servier Platform License, collectively referred to as the Servier Agreements. Pursuant to the terms of the Servier Agreements, we, along with Servier, will initially pursue five bispecific therapeutic programs. These 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 IO 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 United States for up to four programs, including any potential expansion, while Servier will be responsible for development and commercialization of the other programs worldwide.

Under the Servier Agreements, we received an upfront payment of €30.0 million (approximately $32.0 million) and have achieved two preclinical milestones related to PRS-344. We may also receive additional development-dependent and commercial milestone payments for each program. The total development, regulatory and sales-based milestone payments to us

could exceed €1.7 billion during 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 of the Servier Agreements ends upon the expiration of all of Servier's payment obligations under such Servier Agreement. The Servier Agreements may be terminated by either of us for material breach upon 90 days' or 120 days' notice of a material breach, with respect to the Servier Collaboration Agreement and the Servier Platform License, 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 Servier Agreement have been followed. The Servier 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 Servier Platform License will terminate upon termination of the Servier Collaboration Agreement, on a product-by-product and/or country-by-country basis.

Our collaboration with Seattle Genetics

On February 8, 2018, we entered into the Seattle Genetics Collaboration Agreement and a non-exclusive Anticalin platform technology license agreement with Seattle Genetics, or the Seattle Genetics Platform License, collectively referred to as the Seattle Genetics Agreements, pursuant to which the parties will develop multiple targeted bispecific IO treatments for solid tumors and blood cancers.

Under the terms of the Seattle Genetics Agreements, Seattle Genetics paid us a $30 million upfront fee, will pay tiered royalties on net sales up to the low double-digits, and will pay us up to $1.2 billion in total success-based payments across three product candidates. The companies will pursue multiple antibody-Anticalin fusion proteins during a research phase, and Seattle Genetics has the option to select up to three therapeutic programs for further development. Prior to the initiation of a pivotal trial, we may opt into global co-development and U.S. commercialization of the second program and share in global costs and profits on a 50/50 basis. Seattle Genetics will solely develop, fund and commercialize up to two other programs. Seattle Genetics may also decide to select additional candidates from the initial research phase for further development in return for the payment to us of additional fees, milestone payments, and royalties.

The term of each of the Seattle Genetics Agreements ends upon the expiration of all of Seattle Genetics' payment obligations under such Seattle Genetics Agreement. The Seattle Genetics Collaboration Agreement may be terminated by Seattle Genetics on a product-by-product basis for convenience beginning 12 months after its effective date upon 90 days' notice or, for any program where a pivotal study has been initiated, upon 180 days' notice. Any program may be terminated at Seattle Genetics' option. If any program is terminated by Seattle Genetics after a pre-defined pre-clinical stage, we will have full rights to continue such program. If any program is terminated by Seattle Genetics prior to such pre-defined pre-clinical stage, we will have the right to continue to develop such program but will be obligated to offer a co-development option to Seattle Genetics for such program. The Seattle Genetics Collaboration Agreement may also be terminated by Seattle Genetics or us for an uncured material breach by the other party upon 90 days' notice, subject to extension for an additional 90 days if the material breach relates to diligence obligations and subject, in all cases, to dispute resolution procedures. The Seattle Genetics Collaboration Agreement may also be terminated due to the other party's insolvency and may in certain instances, including for reasons of safety, be terminated on a product-by-product basis. Each party may also terminate the Seattle Genetics Agreements if the other party challenges the validity of any patents licensed under the Seattle Genetics Agreements, subject to certain exceptions. The Seattle Genetics Platform License will terminate upon termination of the Seattle Genetics Collaboration Agreement, whether in its entirety or on a product-by-product basis.

Our License Agreements are older than our Strategic Partnerships and relate to non-strategic therapeutic areas, or do not provide us with co-development and co-commercialization rights. A brief summary of certain terms of selected License Agreements are provided below.

Our ASKA Option Agreement

On February 27, 2017, we entered into an exclusive option agreement, or the ASKA Option Agreement, with ASKA Pharmaceutical Co., Ltd., or ASKA, an exclusive option to license development and commercial rights to our anemia drug, PRS-080, in Japan, South Korea and certain other Asian markets following completion of a multi-dose phase 2a study to be conducted by us in dialysis-dependent anemia patients. On January 20, 2020, ASKA notified us that it does not intend to exercise its option to obtain an exclusive license to develop and commercialize the PRS-080. ASKA's decision was based on a strategic portfolio review as well as certain commercial considerations. The term of the ASKA Option Agreement ended as of the date of ASKA's notification of its decision not to exercise its option rights. In view of the Company's strategic focus on IO

and respiratory diseases, including the continued development of PRS-343, PRS-344, and PRS-060/AZD1402, the Company does not intend to continue the development of PRS-080.

Our collaboration with Roche

In December 2015, we entered into a research collaboration and license agreement, or the Roche Agreement, with F. Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., or Roche, for the research, development, and commercialization of Anticalin-based drug candidates against a predefined, undisclosed target in cancer immune therapy selected by Roche. Roche notified us of the termination of the Roche Agreement, effective August 21, 2018. As a result, any Anticalin proteins generated prior to termination are wholly owned by us following termination of the Roche Agreement. Prior to the termination of the Roche Agreement, our platform technology successfully produced a number of discovery hits specific for the target from our Anticalin libraries. Our drug supply agreement with Roche for access to atezolizumab, an approved PD-L1 inhibitor, for a combination study of PRS-343 and atezolizumab in HER2-positive cancer patients is not impacted by the termination of the Roche Agreement.

In-License Agreements

In addition to the Strategic Licenses and Other License Agreements, we have in-licensed a number of technologies and therapeutics, hereinafter referred to as the In-License Agreements, to advance our pipeline and programs, some of which are described below.

TUM License

On July 4, 2003, we entered into our TUM License which was subsequently renewed and amended on July 26, 2007. The TUM License 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 TUM License, 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 TUM License, we hold a worldwide exclusive license under our agreement with TUM to multiple patents and patent applications related to certain Anticalin proteins and libraries. 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 license 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 license 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.

Pieris and TUM initiated discussions in the second quarter of 2018 to clarify, expand and restructure the TUM License, including the parties’ obligations under such license agreement. The parties' discussions relate to revised commercial terms and to re-initiating additional collaborations between faculty at TUM and Pieris. While an amended and restated license agreement

has not yet been completed, we intend to enter into such an amendment. These discussions may also lead to an increase in our collaborative research activities with TUM.

We recorded the probable expected impact of the amendment in research and development expense in 2018, which was an increase in our financial obligations associated with the TUM License of approximately $2.3 million for amounts that would be due in 2019 for 2018 and 2017 sub-licensing activities. This liability was paid in full during the year ended December 31, 2019.

Enumeral License Agreements

In the second quarter of 2016, we entered into two license agreements, collectively the PD-1 In-License, with Enumeral Biomedical Holdings, Inc., or Enumeral, pursuant to which we in-licensed certain 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 PD-1 In-License, we acquired a non-exclusive worldwide license (except in the exclusive field of licensed antibodies fused to Anticalin proteins in the oncology area) 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 for use in the oncology area. On January 29, 2018, Enumeral filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the Bankruptcy Court for the District of Massachusetts, or the Bankruptcy Court. In connection with those proceedings, Enumeral transferred the intellectual property related to the PD-1 In-License to PD-1 Acquisition Group, LLC, or Acquisition Group, who have assumed the rights and obligations of Enumeral with respect to the PD-1 In-License.

Under the terms of the PD-1 In-License, we are obliged to pay to Acquisition Group 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 Acquisition Group will 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 Acquisition Group. Payment obligations terminate on a product-by-product and country-by-country basis on the later of 10 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 PD-1 In-License that cover the manufacture, use, offer for sale, sale or import of a product incorporating the Enumeral antibody.

The term of the PD-1 In-License ends upon the expiration of the last to expire patent covered under the license unless earlier terminated by us or Acquisition Group in accordance with the terms of the PD-1 In-License.

Kelun License Agreement

In connection with our efforts to develop multispecific Anticalin-based proteins designed to engage immunomodulatory targets, during the second quarter of 2017, we entered into a license and transfer agreement, or the Kelun Agreement, with Sichuan Kelun-Biotech Biopharmaceutical Co. Ltd., or Kelun. Under the Kelun Agreement, Kelun has granted to us a non-exclusive worldwide license (with the right to sublicense) under certain intellectual property owned or controlled by Kelun to research, develop, manufacture, and commercialize bi- and multi- specific fusion proteins that include an antibody developed by Kelun specific for an undisclosed target and one or more Anticalin proteins.

Government Regulation

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, sales, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory requirements, require the expenditure of substantial time and financial resources.

U.S. Government regulation of drug and biological products

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biologics, also under the Public Health Service Act, or the PHSA, and their implementing regulations. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or biologics license applications, or BLAs, or the agency's 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 brought by the FDA and the U.S. Department of Justice or other governmental entities.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, current good clinical practices, or cGCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA for marketing approval, including payment of application user fees;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites to assure compliance with cGCPs and the integrity of the clinical data submitted in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including satisfactory completion of an FDA advisory committee review of the product candidate, where appropriate or if applicable, prior to any commercial marketing or sale of the product in the United States.

Preclinical studies

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies, to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including good laboratory practices, or GLP, regulations for safety and toxicology studies. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug candidate is submitted to the FDA and human clinical trials have been initiated.

Human clinical trials in support of an NDA or BLA

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. 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. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and 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. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Clinical holds may also be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

In addition, an IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review and re-approve the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial.

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

- ***Phase 1:*** 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 2:*** 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 3:*** Clinical trials are undertaken with an expanded patient population to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often 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. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. 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 clinical protocol, cGCP, or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2, and before submission of an NDA or BLA. 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 2 meeting to discuss their phase 2 clinical results with the agency and to present their plans for the pivotal phase 3 studies that they believe will support approval of the new drug or biological product.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the drug or biological product 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, potency and purity of the final drug or biological product. For biological products in particular, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. 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.

Marketing application submission and FDA review

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. Our Anticalin-based product candidates are proteins that will be regulated as biological products subject to the BLA marketing pathway. BLA in particular must contain proof of the biological product candidate's safety, purity, potency and efficacy for its proposed indication or indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. Under federal law, the fee for the submission of an NDA or BLA is substantial (for example, for FY2020 this application fee exceeds $2.9 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than $300,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

The FDA conducts a preliminary review of all NDAs and BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review. As noted above, the FDA has agreed to specified performance goals in the review process of NDAs and BLAs. Applications are meant to be reviewed within ten months from the date it is accepted for submission or filing, and the applications for "priority review" products are meant to be reviewed within six months from the date the application is accepted for submission or filing, as discussed in more detail below. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with "priority review." For all BLAs and new molecular entity, or NME, NDAs, the ten and six-month time periods run from the filing date; for all other original applications, the ten and six-month time periods run from the submission date. Despite these review goals, it is not uncommon for FDA review of an NDA or BLA to extend beyond the goal date.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with cGCP requirements and the integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer any NDA or BLA, including applications for novel biologic candidates which present difficult questions of safety or efficacy, to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts that reviews, evaluates and provides a 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 considers such recommendations when making final decisions on approval. The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement to a BLA must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or the FDASIA, enacted in 2012, made permanent the PREA to require a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials or other clinical development programs.

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. 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. On the basis of the FDA's evaluation of the NDA or BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. 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 testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the

NDA or BLA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, with the enactment of FDASIA in 2012, Congress created a new regulatory program for product candidates designated by FDA as "breakthrough therapies" upon a request made by the IND sponsors. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval of their respective marketing applications. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

Finally, the FDA may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA or for an NME NDA from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated approval pathway

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 from the FDA 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. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product 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 to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Patent term restoration

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 14 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, or the USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Reference product exclusivity for biological products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. A federal district court ruling in Texas in 2018 struck down the Affordable Care Act in its entirety based on constitutionality last year, and in December 2019 the Fifth Circuit Court of Appeals upheld lower court's finding that the individual mandate in the law is unconstitutional. However, the Fifth Circuit also reversed and remanded the case to the district court to determine if other reforms enacted as part of the Affordable Care Act but not specifically related to the individual mandate or health insurance, including the BPCIA, could be severed from the rest of the Affordable Care Act so as not to be declared invalid. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business. To date, the FDA has approved a number of biosimilars, and numerous biosimilars have been approved in Europe. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

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 can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States.

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.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, the 12-year exclusivity period will be extended for an additional six months. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Orphan drug designation and exclusivity

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 United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States 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 for treatment of the same indication or disease.

Post-approval requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or an NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics 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. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including voluntary recall and regulatory sanctions as described below.

Once an approval or clearance of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. 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.

Regulation outside of the United States

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 outside of the United States. Whether or not we obtain FDA approval for a product candidate, 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. It is not yet clear how the United Kingdom’s withdrawal from the European Union, which took place on January 31, 2020, will affect the approval of medicinal products in the UK. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or

jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union drug development, review and approval

In the European Union, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP, and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an IMPD (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, and where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents. All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the competent national authority and the Ethics Committee of the Member State where they occurred.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted and it is anticipated to come into application in late 2020 or early 2021. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the “EU portal”; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

To obtain a marketing authorization of a drug in the European Union, we may submit marketing authorization applications, or MAA, either under the so-called centralized or national authorization procedures.

Centralized procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency, or EMA, that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National authorization procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Under the above described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Conditional approval

In specific circumstances, E.U. legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

European Union regulatory exclusivity

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

European Union orphan designation and exclusivity

The criteria for designating an orphan medicinal product in the European Union, are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition

affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

PRIME designation

The EMA grants access to the Priority Medicines, or PRIME, program to investigational medicines for which it determines there to be preliminary data available showing the potential to address an unmet medical need and bring a major therapeutic advantage to patients. As part of the program, EMA provides early and enhanced dialogue and support to optimize the development of eligible medicines and speed up their evaluation, aiming to bring promising treatments to patients sooner.

Periods of authorization and renewals

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

Rest of the world regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage, pricing and reimbursement

Sales of pharmaceutical products approved by the FDA will depend in significant part on the availability of third-party coverage and reimbursement for the products. Third-party payors include government healthcare programs in the United States such as Medicare and Medicaid, 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. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to

specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. 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. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. 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. Other member states allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. 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.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other U.S. health care laws and regulations

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare and Medicaid. These laws include:

- the federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value to physicians, teaching hospitals, and certain advanced non-physician health care practitioners and physician ownership and investment interests;

- the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials, which prohibit U.S. companies and their employees, officers, and representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official (including, potentially, healthcare professionals in countries in which we operate or may sell our products), government staff member, political party, or political candidate to obtain or retain business or to otherwise seek favorable treatment; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by nongovernmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Health care reform in the United States and potential changes to health care laws

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. 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 not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, a primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the U.S. Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The current Presidential administration and members of the U.S. Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Cuts and Jobs Acts was enacted in 2017, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. As noted above, a 2018 federal district court ruling struck down the Affordable Care Act in its entirety although the Fifth Circuit Court of Appeals recently limited it to the individual mandate and remanded the case to the district court to determine if other reforms not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act that affect health care expenditures. There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical and biologic products. Notably, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the

Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Corporate Information

On December 17, 2014, Pieris Pharmaceuticals, Inc., or 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 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.

Upon the closing of the Acquisition on December 17, 2014, Pieris ceased to be a "shell company" under applicable rules of the Securities and Exchange Commission, or the SEC.

As of December 31, 2019, we no longer qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As such, we are no longer eligible to take advantage of certain reduced disclosure and other requirements that are otherwise applicable to public companies, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

Rule 12b-2 of the Exchange Act establishes a class of company called a "smaller reporting company," which effective September 10, 2018, was amended to include companies with a public float of less than $250 million as of the last business day of their most recently completed second fiscal quarter or, if such public float is less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year for which audited financial statements are available. For the year ended December 31, 2019, we qualify as a smaller reporting company.

As a smaller reporting company, we are eligible to and have taken 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. These exemptions include, but are not limited to, reduced disclosure obligations regarding executive compensation in our periodic and annual reports, exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures, and reduced financial statement disclosure in our 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 a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of this classification. We will remain a smaller reporting company until we have a public float of $250 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 December 31, 2019, we had 114 full-time employees and 13 permanent part-time employees. None of our employees are 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 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 on Form 10-K 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 Annual Report on Form 10-K, 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-K contains 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, Capital Requirements, Managing our Growth and Other Legal Compliance Matters

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 commercial sales revenue and are not profitable and have incurred losses since our inception in 2001. For the years ended December 31, 2019 and 2018 we reported net loss of $25.5 million and $26.8 million, respectively. As of December 31, 2019, we had an accumulated deficit of $174.2 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 respiratory and IO programs. Our lead respiratory drug candidate PRS-060/AZD1402, in partnership with AstraZeneca, is currently in phase 1 MAD studies. Our IO program includes our lead IO drug candidate, PRS-343, which is currently in phase 1 escalation studies alone and in combination with atezolizumab. We have additional IO partnered programs with Servier and Seattle Genetics. Together these programs which will result in our continued incurrence of significant research, development and other expenses and resources. If our research and development efforts, including preclinical studies or 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. In addition, the failure of one drug candidate or program may have an adverse impact on other drug candidates and programs that include our class of Anticalin proteins. 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 are highly dependent on the success of PRS-060/AZD1402, our lead candidate in our respiratory pipeline, and PRS-343, the lead candidate in our IO pipeline. We are executing a broad development program for each of PRS-060/AZD1402 and PRS-343 and clinical and regulatory outcomes for each of PRS-060/AZD1402 and PRS-343, if not successful, will significantly harm our business.

Our future success is highly dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize PRS-060/AZD1402 and PRS-343. In general, most early-stage investigatory drugs, including inhaled therapeutics such as PRS-060/AZD1402 and oncology drug candidates such as PRS-343, do not become approved drugs. Accordingly, there is a very meaningful risk that PRS-060/AZD1402 and PRS-343 will not succeed in one or more

clinical trials sufficient to support one or more regulatory approvals. To date, clinical and preclinical outcomes from PRS-060/AZD1402 and PRS-343 have had a significant impact on our market valuation, financial position, and business prospects, and we expect this to continue in future periods. If one or more clinical trials of PRS-060/AZD1402 or PRS-343 is not successful, it would materially harm our market valuation, prospects, financial condition and results of operations.

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 some or all of our product development programs or commercialization efforts and could cause our business to fail.

Our operations have consumed substantial amounts of cash since our inception. We expect to need substantial additional funding to pursue the preclinical and clinical development of our drug candidates, as well as to 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 programs, 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 continue to advance, expand, and monitor the performance of our preclinical and clinical programs, such as PRS-060/AZD1402, PRS-343, and PRS-344, as well as additional programs that we advance through preclinical development and into the clinic and whose performance we monitor. 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 the receipt of up-front and milestone payments due under 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. Our ability to secure additional funding from those or other sources could be significantly impacted by a multitude of events that are beyond our control, including, but not limited to, changes in the macroeconomic environment and other events affecting the stock market, including the availability of research and other information, favorable or unfavorable, published by securities or industry analysts and news agencies.

Raising capital through the sale of equity or securities convertible into equity 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 receipt of only a portion of the revenues associated with the potential commercialization of our partnered drug candidates.

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 2001, and since that time our focus has been on discovery of Anticalin-brand drug candidates. We are currently conducting clinical development of both PRS-060/AZD1402, in partnership with AstraZeneca, and PRS-343, and we are also advancing other drug candidates through preclinical development with the intention of initiating additional clinical-stage programs. In addition to our focus on respiratory diseases and IO, we are also exploring additional indications that may be suitable for Anticalin-brand drug therapeutics. Our drug candidates are in the 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 experience with clinical-stage operations, including manufacturing required to support clinical activities 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 discovery and development operations can only provide limited operating results upon which investors 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, financial and other 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 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 Anticalin platform and 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 raise capital, expand our business, develop our drug candidates 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, including the United States, Europe (including Germany) 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 and changes in tax laws;
- 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, and related compliance with employment, immigration and labor laws for employees or other staff living abroad;
- restrictions imposed by local labor practices and laws on our business and operations;

- economic weakness, including inflation, or 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;
- compliance with the FCPA and other anti-corruption and anti-bribery laws;
- unexpected changes in 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 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.

Due to our operations outside of the United States, we are exposed to market risk related to changes in foreign currency exchange rates. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, our financial condition, the results of our operations or our cash flows. 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 are recorded in non-U.S. entities. As such, our 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.

We incur currency transaction risks whenever we enter into either a purchase or a sale transaction using a currency other than the Euro, our functional currency, particularly in 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.

As we realize our strategy to expand in the United States, Germany, Australia and elsewhere 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.

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 and wastes. 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 developed, 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, European Union (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 our Anticalin drug candidates and the materials used in the production of such 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 EU regulation on classification, labeling and packaging of substances and mixtures, or CLP, and under other regulations in the United States or other countries related to the clinical development of our drug candidates (including, for example, submissions to regulatory authorities such as the FDA and EMA as well as submissions related to obtaining a non-proprietary, or INN and USAN, name for our clinical drug candidates to the World Health Organization, or the WHO, and United States Adopted Name Council, or the USAN Council), 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 these regulations may have a further negative impact on 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, 2019, we had net operating loss carryforwards for United States federal income tax purposes of $20.1 million and net operating loss carryforwards for state income tax purposes of $26.7 million. Tax loss carryforwards that were generated prior to December 31, 2017 expire through 2037, U.S. federal generated after that date do not expire. State loss carryforwards expire starting in 2035. In the United States, utilization of the net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss 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. We have 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, 2019, we had German corporate income tax and trade tax net operating loss carryforwards of approximately $90.5 million and $89.7 million, respectively, which may be used to reduce our future taxable income in Germany. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) by $1.2 million plus 60% of the exceeding taxable income and trade profit of such period and do not expire. 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.

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, adverse public health events and other events beyond our control, the occurrence of which could materially harm our business and drug development efforts.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, hacking, ransomware, cyber-attacks, 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 and operations. 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 such 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, natural disasters, adverse public health events 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. For example, in December 2019, a novel strain of coronavirus was first identified in Wuhan, Hubei Province, China. Any outbreak of contagious diseases such as coronavirus, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers. Such disruptions may result in material delays in the advancement of our programs, including in the initiation or conclusion of drug substance or drug product manufacturing campaigns or in the initiation or conclusion of any clinical study. In addition, given that it impacts the respiratory tract, the novel strain of coronavirus may negatively impact our ability to conduct clinical studies in respiratory diseases, including asthma. Any disruption to our operations or the operations of our collaborators or suppliers would likely impact our drug development efforts, operating results, and our financial condition. The extent to which the coronavirus may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus.

As another example, certain of our development efforts, particularly those related to our Phase 1 study of PRS-060/AZD1402, which are being conducted in Australia, are located in geographical areas that are known to be prone to certain natural disasters and weather events, including wildfires. In 2019 and continuing into 2020, dozens of wildfires have erupted in New South Wales, Australia, prompting the government of Australia to declare a state of emergency in November 2019. Should such a natural disaster occur that causes disruption to our development efforts in Australia or elsewhere, thereby impeding our ability or the ability of our collaborators to timely conduct our clinical trials, our ability to conduct our business could be severely restricted, and our business and results of operations could be adversely affected as a result. The extent to which the wildfires in Australia or any natural disaster may impact our results will depend on future developments, which are highly uncertain and cannot be predicted.

Although we carry business interruption insurance for our operations in Germany and the United States to protect us against losses or damages resulting from various disasters, we cannot assure you that our insurance coverage will be sufficient to satisfy any damages and losses. If our facilities are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial position, results of operations, and prospects.

Our current operations are largely concentrated in two locations and any events affecting these locations may have material adverse consequences.

Our current operations are carried out primarily in our facilities located in Hallbergmoos, Germany and Boston, Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure, or other natural or man-made accidents, or incidents that prevent us from fully utilizing our facilities in these two locations, may have a material adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates, or interruption of our business operations. In the event of an accident or incident at these facilities, we cannot assure you that our insurance coverage will be sufficient to satisfy any damages and losses. If our facilities are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial position, results of operations, and prospects.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification

laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, in May 2016, the EU Parliament adopted the comprehensive General Data Privacy Regulation, or the GDPR to, among other things, impose more stringent data protection requirements for processors and controllers of personal data and provide for greater penalties and fines for noncompliance, including fines in amounts up to €20 million or 4% of total worldwide annual turnover, whichever is higher. The GDPR became fully effective in May 2018. In addition, in 2018, California adopted a new privacy law, scheduled to go into effect on January 1, 2020, that borrows heavily from the GDPR. Complying with the enhanced obligations imposed by the GDPR and other applicable international and U.S. privacy laws and regulations may result in significant costs to our business and require us to amend certain of our business practices. Further, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The future enactment of more restrictive laws, rules or regulations and/or future enforcement actions or investigations could have a materially adverse impact on us through increased costs or restrictions on our businesses, and noncompliance could result in regulatory penalties and significant legal liability.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or to cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

We are subject to income and other taxes in the United States and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA, which significantly reforms the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a “worldwide” system of taxation to a territorial system. Our net deferred tax assets and liabilities were revalued at the newly enacted U.S. corporate rate in 2017.

Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA, whether adverse or favorable, remains uncertain and may not become evident for some period of time, and our business and financial condition could be adversely affected as a result. The impact of this tax reform on holders of our securities is also uncertain and could be adverse. This Annual Report on Form 10-K does not discuss any such tax legislation or the manner in which it might affect us or

purchasers of our securities. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our securities.

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. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning in December 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 asthma and cancer markets is intense. We have competitors in the United States and internationally, including major multinational pharmaceutical companies, fully integrated pharmaceutical and 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 compete with drug candidates in our pipeline.

Drug candidates interfering with the function of type 2 helper T-cells, or Th2, the biological pathway for PRS-060/AZD1402, and thus competing with PRS-060/AZD1402, include those that are being developed by Sanofi/Regeneron (dupilumab), GSK (mepolizumab), Teva (reslizumab), benralizumab (AstraZeneca, IL-5Rá), REGN-3500/SAR-440340 (Regeneron/Sanofi, IL-33), and Amgen/AstraZeneca (tezepelumab). Drugs targeting immunomodulatory targets and thus competing with our 300-series programs include those that are currently marketed by Bristol-Myers Squibb (ipilimumab, nivolumab), Merck & Co (pembrolizumab), Roche (atezolizumab), Merck Serono/Pfizer (avelumab) and AstraZeneca (durvalumab),among others and drug candidates being developed by Bristol-Myers Squibb (for example, urelumab/anti-CD137), Pfizer (for example, utomilumab/anti-4-1BB) and other clinical stage drug candidates also compete with our proprietary and partnered IO programs. Additionally, a number of other companies, such as Amgen, Affimed, Macrogenics, F-Star, Molecular Partners, Xencor, Immunocore and Zymeworks, also pursue multispecific approaches in oncology, which therapies are in clinical or preclinical development. For additional information about our third-party drug candidates that could compete with the drug candidates in our pipeline, see "Business--Competition."

These existing or future competing products may provide therapeutic convenience or clinical or other benefits for a specific indication greater 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 our products' 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 claim 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. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources.

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. While we currently carry insurance that we believe is appropriate for a company at our stage of development, including with respect to our ongoing clinical trials and studies, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer.

In the future, we will seek to obtain appropriate insurance coverage with respect to any future clinical trials of our other drug candidates, 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. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business, operations, and our prospects.

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 December 31, 2019, we have 114 full-time employees and 13 permanent 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.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, commonly referred to as "Brexit." The United Kingdom officially withdrew from the European Union on January 31, 2020. The British government is continuing to negotiate the terms of the United Kingdom's future relationship with the European Union during a transitionary period that is due to end on December 31, 2020. A substantial amount of uncertainty remains regarding the outcome of the ongoing negotiations. Depending on the terms of Brexit after the conclusion of the transition period, the extent Brexit will impact the business and regulatory environment in the United Kingdom, the rest of the European Union, or other countries, remains unknown. Brexit could, among other outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the European Union, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. Brexit could also result in similar referendums or votes in other European countries in which we do business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications Brexit will have and how it will affect us.

For example, Brexit could result in the United Kingdom or the European Union significantly altering its regulations affecting the clearance or approval of our product candidates that are developed in the United Kingdom or the European Union. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the United Kingdom, the European Union and elsewhere. In addition, the announcement of Brexit and the withdrawal of the United Kingdom from the European Union have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity and financial condition.

As another example, we currently rely on multiple CMOs for all of our clinical supplies, including APIs, drug substances and finished drug products, and label and packaging for our preclinical research and clinical trials, including the phase 1 study for PRS-060/AZD1402 and the phase 1 studies for PRS-343, and any tariffs, differing regulatory requirements and other restrictions on the free movement of goods between the United Kingdom and the European Union that result from Brexit may have an adverse impact on this part of our supply chain. This could therefore negatively impact our clinical operations and, in particular, the advancement of our lead respiratory program, PRS-060/AZD1402, which would adversely affect our business, our results of operations and financial condition.

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 respiratory programs, including PRS-060/AZD1402, our other partnered programs with AstraZeneca, our proprietary respiratory programs, our proprietary IO programs, particularly PRS-343, our partnered programs with Servier including PRS-344, our partnered programs with Seattle Genetics, as well as our other programs. In partnership with AstraZeneca, PRS-060/AZD1402 is in clinical development with a completed phase 1 SAD study for which data was reported in November 2018, and an ongoing phase 1 MAD study initiated in July 2018. For PRS-343, a phase 1 study was initiated in the second quarter of 2017 and a phase 1 study of the drug candidate in combination with

atezolizumab was initiated in the third quarter of 2018. We are engaged in research and development activities with respect to a number of additional drug candidates and programs. All of our other drug candidates are in the discovery or early preclinical to IND-enabling stage. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of PRS-060/AZD1402, PRS-343, PRS 344 and our other IO and respiratory 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 with successful outcomes;
- manage preclinical, manufacturing and clinical activities;
- obtain regulatory approval from the FDA and other comparable foreign regulatory authorities;
- establish manufacturing relationships for the clinical and post-approval supply of the applicable drug candidate in compliance with all regulatory requirements;
- build a commercial sales and marketing team, either internally or by contract with third parties;
- establish and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- develop and implement marketing strategies for successful commercial launch of our product candidates, if and when approved;
- secure acceptance of our products, if and when approved, by patients, from the relevant medical communities and from third-party payors;
- compete effectively with other therapies;
- establish and maintain adequate health care coverage and reimbursement;
- ensure continued compliance with any post-marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trials or the elements of any post-marketing Risk Evaluation and Mitigation Strategy, or REMS, that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks;
- maintain continued acceptable safety profile of the product candidates following approval; and
- invest significant additional cash in each of the above activities.

If we are unable to address one or more of these factors in a timely manner or at all, we could experience significant delays in the successful commercialization of, or an inability to successfully commercialize, our product candidates, which would materially harm our business. If we do not receive regulatory approvals for one or more of our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, competitors products in the same markets, market acceptance, and other factors. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

Clinical testing of PRS-060/AZD1402 and PRS-343 was initiated in 2017, while clinical testing for other programs, including our other IO programs, has not yet commenced, and the results of any future clinical trials or preclinical studies of these programs, if unsuccessful, could lead to our abandonment of the development of those drug candidates. 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 has been conducted to date or will be conducted in the 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 and other nonclinical studies and clinical trials, and because of our limited operating experience, we may discover that our own development activities are not in compliance with applicable regulatory requirements or are otherwise deficient, and therefore, determine that the development of our drug candidates on the basis of those trials and studies is not warranted or will be delayed.

We have also entered into license, partnership, and option arrangements, such as with Servier, AstraZeneca, Seattle Genetics, and ASKA, which has been terminated, relating to certain drug candidates and may continue to do so in the future. Under some of these arrangements, the development of some of those drug candidates has been, or in the future may be, conducted wholly by such partners or 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 some of such partners have provided information regarding those drug candidates and the related studies conducted to date, including certain data that is included in this Annual Report on Form 10-K, we have not received and may not receive in the future comprehensive information regarding all of those development activities, including the raw data from certain 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 may have limited or no input on the development 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, including our phase 1 study with PRS-060/AZD1402 in Australia and our phase 1 study with PRS-343 in the United States, and our anticipated future clinical trials, have been, are being, or may in the future be conducted in or outside the United States, including in Europe or Australia. We may also conduct some of our future development activities in other countries or regions. As a result, although those studies may meet the standards of applicable foreign regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable FDA requirements and also may not meet the requirements of the applicable regulatory authorities in other foreign countries in which we desire to pursue marketing approval.

If the studies conducted by us or our partners or collaborators do not comply 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 additional studies, which would severely delay or prevent 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 efforts are focused 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 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 to companies that focus on more traditional drug classes, such as antibodies and small molecules, we believe that 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 advance 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 have good drug-like properties (target affinity, stability, half-life, etc.) and 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, clinical trials are 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 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 early-stage 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 initiated phase 1 studies for PRS-060/AZD1402 and PRS-343 in 2017 and initiated a phase 1 study of PRS-343 in combination with atezolizumab in 2018. 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, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay in reaching, or failure to reach, 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;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable volunteers or patients to participate in a trial;
- delay or failure in developing and validating companion diagnostics, if they are deemed necessary, on a timely basis;
- failure of patients to complete a trial or return for post-treatment follow-up;
- inability to monitor patients adequately during or after treatment;
- clinical sites and investigators deviating from trial protocols, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by the FDA or comparable foreign regulatory authority due to observed safety findings or other reasons;
- negative or inconclusive results in our clinical trials, and our decision to or regulators' requirement that we conduct additional non-clinical studies, clinical trials or that we abandon one or more of our product development programs; or

- inability to manufacture sufficient quantities of a drug candidate of acceptable quality for use in clinical trials.

We rely and plan to continue to rely on CROs, CMOs 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 and CMOs governing their contracted 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 or CMO's compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements, or its adherence to agreed-upon time schedules and deadlines, and a future CRO's or CMO'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, by a Data Safety Monitoring Board, or DSMB, or by the FDA or EMA, or other regulatory authority. A suspension or termination
may be 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, 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, or changes in governmental regulations or administrative actions. Therefore, we cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates.

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 focusing 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 size and nature of the target patient population;
- the severity of the disease under investigation;
- the frequency of the molecular alteration we are seeking to target in the applicable trial;
- the patient eligibility criteria for the clinical trial in question;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the perceived risks and benefits of the drug candidate under study in the clinical trial;
- the approval and availability of other therapies to treat the disease or disorder that is being investigated in 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;
- the presence of other drug candidates in clinical development for the same indication or against the same target; and
- the proximity and availability of clinical trial sites for prospective participants.

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 clinical trials.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. In particular, no Anticalin-based drug products have been approved or commercialized in any jurisdiction, and the outcome of our preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

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 where regulations differ. We are not permitted to market our biological product candidates in the United States until we receive the respective approval of a 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, if approval is obtained at all, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials. We have not submitted a marketing application such as a BLA to the FDA, a marketing authorisation application, or MAA, to the EMA, or any similar application to any other jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third-party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Moreover, we have not 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, or could be delayed in receiving, 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;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA, EMA or comparable foreign regulatory authorities;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and
- the change of the medical standard of care or the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner that renders 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-060/AZD1402, PRS-343, PRS-344, our other respiratory and IO programs, our discovery stage programs, or any other drug candidates we are developing or 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 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 (referred to as "conditional" or "accelerated" approval depending on the jurisdiction), 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.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. The United Kingdom officially withdrew from the European Union on January 31, 2020. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals in the United Kingdom, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and reduce our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

Furthermore, other European countries may seek to conduct referenda with respect to continuing membership with the European Union. We do not know to what extent Brexit or other comparable initiatives, or any resulting changes, would affect our ability to conduct clinical trials or obtain marketing approval in these jurisdictions, and each could materially impact our ability to conduct clinical trials or obtain marketing approval on a timely basis, or at all.

Our failure to obtain marketing approval in jurisdictions other than the United States and Europe would prevent our product candidates from being marketed in these other jurisdictions. Any approval that we are granted for our product candidates in the United States or Europe would not assure approval of product candidates in the other or in any other jurisdiction.

In order to market and sell our future products in jurisdictions other than the United States or Europe, we or our third-party collaborators must obtain separate marketing approvals in that jurisdiction and comply with numerous and varying 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, some countries or regions outside the United States and Europe require approval of the sales price of a drug before it can be marketed in that country or region. In many countries, separate procedures must be followed to obtain reimbursement. Moreover, approval by the FDA, EMA 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.

Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit their commercial potential, or result in significant negative consequences following marketing approval, if marketing approval is obtained.

Undesirable side effects caused by our product candidates could cause us or the FDA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities of our product candidates. In the event that our clinical trials produce undesirable side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. In addition to this, the product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, specific warnings or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients, or we may be required to implement a REMS to ensure that the benefits of the product outweigh the risks;
- we may be required to change the way such product candidates are distributed or administered, or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;

- we may decide to recall such product candidates from the marketplace after they are approved;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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 forgo 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, or if market conditions change, 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 properly 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 clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or otherwise conduct the trials as required or comply with regulatory requirements, we may not be able to obtain regulatory approval for our drug candidates, commercialize our product candidates when expected or at all, and our business could be substantially harmed.

We depend upon independent investigators and contractors, such as CROs, universities and medical institutions, to conduct our clinical trials and preclinical studies. We rely upon, and plan to continue to rely upon, such third-party entities to execute our clinical trials and preclinical studies and to monitor and manage data produced by and relating to those studies and trials. However, in the future we may not be able to 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 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 future sales of such drug candidate. Any agreements governing our relationships with CROs or other contractors with whom we currently engage or 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.

If our relationships with any third parties conducting our studies are terminated, we may be unable to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Switching or adding third parties to conduct our studies involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with third parties conducting our studies, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material and adverse effect on our business, financial condition and results of operations.

We rely and expect to continue to rely completely on third parties to formulate and manufacture our preclinical, clinical trial and commercial 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 our clinical trials and preclinical studies 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 CMOs for the clinical-stage manufacturing of certain drug candidates, including PRS-060/AZD1402, PRS-343, PRS-344, and others. 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 receives 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 qualified potential manufacturers is limited. Following BLA approval, if successful, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections.
- 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 and commercial needs, if any.
- Our future CMOs 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 some state agencies to ensure strict compliance with cGMP regulations and other U.S. and corresponding foreign requirements. 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 or the commercialization of our drug candidates, could result in higher costs or could deprive us of potential product revenues.

Although our agreements with our CMOs require them to perform according to certain cGMP requirements such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If any of our CMOs cannot successfully manufacture material that conforms to our specifications

and the 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 CMO that can comply with such requirements, which we may not be able to do. Any such failure by any of our CMOs 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 CMOs' 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 of 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 CMOs are governed by the service agreements between us and each of the manufacturers. 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 such 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 we and the other party previously believed that we both had a mutual understanding of such terms.

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 with the diligence or 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.

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, along with 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 both U.S.-based and foreign pharmaceutical and drug development companies, which will lead, finance or otherwise collaborate with us or assist us in the development, manufacturing and marketing of our 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 our 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, in particular with respect to our collaborations with AstraZeneca for the development of PRS-060/AZD1402 and with Servier for the development of PRS-344. 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, manufacturing, marketing or sale of these products. In addition, our collaborative partners may have the right to guide strategy regarding prosecution of relevant patent applications, abandon research projects and/or 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 forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third-party strategic partners. In the event of termination of a collaboration agreement, termination negotiations may result in less than 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 the 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 new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property rights.

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 effort 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, currently including PRS-060/AZD1402 and PRS-344. 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 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 that 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 their collaborations with us without cause, in which event, we might not be able to complete development and commercialization of our drug candidates on our own.

Our collaborative relationships may not produce the financial benefits that we are anticipating, which could cause our business to suffer.

Part of our strategy is to partner with, or out-license selective products to, other pharmaceutical companies in order to mitigate the cost of developing a drug through clinical trials to commercialization. Our ASKA Option Agreement is an example of this strategy. Following the phase 2a study we conducted, ASKA had an option to obtain an exclusive license to develop and commercialize PRS-080 in Japan, South Korea and certain other Asian markets which they did not exercise for strategic reasons. Exercising this option could have made us eligible to receive 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 with further development milestones in additional indications from Japan and other countries within the ASKA territory. If our collaboration with other similar partners is not successful our future revenues and business will be harmed.

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

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

If the FDA or a comparable foreign regulatory authority approves any of our drug candidates, activities such as the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion and record keeping 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. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called “Phase 4 trials”) and post-marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant not-compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or us. If we or our third-party providers, including our CMOs, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products.

In addition, later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in the following, among other things:

- restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- withdrawal of the product from the market;
- product recalls;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;

- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- 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.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product 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 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, third-party payors and other members of the medical community.

Even if we obtain regulatory approval for our drug candidates, the approved products may nonetheless fail to gain sufficient market acceptance among physicians, third-party payors, patients and other members of the medical community, which is critical to commercial success. If an approved product does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any drug candidate for which we receive approval depends on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the size of the market for such 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 safety of the drug candidate as demonstrated through broad commercial distribution;
- the ability to offer our product candidates for sale at competitive prices;
- 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 compared to alternative treatments;
- cost-effectiveness of our product relative to competing products;
- the prevalence and severity of any side effects;
- the adequacy of supply of our product candidates;
- the timing of any such marketing approval in relation to other product approvals;

- any restrictions on concomitant use of other medications;
- support from patient advocacy groups; 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 ability to negotiate, secure and maintain third-party coverage and reimbursement for our product candidates may be affected by political, economic, legal and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any product candidate of ours that receives marketing approval in the future.

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-060/AZD1402, PRS-343, PRS-344 or other product candidates that 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.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell our biological product candidates would adversely impact our business and future results of operations.

Our product candidates for which we intend to seek approval may face generic or biosimilar competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our Anticalin-based product candidates are expected to be regulated by the FDA as biological products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is

uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient's specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Even if we are able to commercialize any of our drug candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or health care reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and biological products vary widely from country to country. Current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product marketing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal health care programs or private health plans in the United States. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided and reimbursement is adequate to cover a

significant portion of the cost of such products. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by federal health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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 including plans announced by the Trump Administration to reform the U.S. pharmaceutical pricing system significantly through rulemaking and executive orders. In addition, existing legislation aimed at patient affordability in the United States such as the Affordable Care Act 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 the member states of 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. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. 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 in order to obtain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products 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 and our business could be adversely affected.

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 have no experience as a company in the sale or marketing of pharmaceutical products. 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 collaborators' strategic interest in the products under development and such collaborators' 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, time-consuming and requiring significant attention of our executive officers to manage. Further, we 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.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk with respect to commercial sales of any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or sites;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- increased insurance costs; and
- the inability to commercialize any products that we may develop.

We have product liability insurance coverage in an amount and on terms and conditions that are customary for similarly situated companies and that are satisfactory to our board of directors. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin conducting more expansive clinical development of, or commercializing, our current product candidates or any potential future product candidate of ours. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our relationships with prescribers, purchasers, third-party payors and patients will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other health care providers and third-party payors will play a primary role in the recommendation, prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain

marketing approval. Restrictions under applicable domestic and foreign health care laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- U.S. federal false claims, false statements and civil monetary penalties laws, including the U.S. False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, that imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;

- the FCPA and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials;

- the U.S. federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act,” which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to physician payments and other transfers of value to physicians and teaching hospitals (and, beginning in 2021, for transfers of value to other health care providers), as well as the ownership and investment interests of physicians and their immediate family members;

- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry;

- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;

- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations, resulting in government enforcement actions.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from federal health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal health care programs.

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, Enumeral and Kelun, we could lose license rights that are important to our business and our operations could be materially harmed.

We in-license significant intellectual property related to our Anticalin platforms from TUM. Under the terms of the TUM License, 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, prosecuting and maintaining the patents assigned or licensed to us under the TUM License.

As consideration for the assignments and licenses, we are obliged to pay milestone payments to TUM on development of our proprietary products claimed by patents assigned or licensed to us by TUM. We are also obliged to pay low single-digit royalties, including annual minimum royalties, on the 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 fees as a function of out-licensing revenues in connection with those patents, or Out-License Fees, 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 TUM License that covers a proprietary product or is sublicensed, as applicable.

Pieris and TUM initiated discussions in the second quarter of 2018 to clarify, expand and restructure the TUM License, including the parties' obligations under such license agreement. The parties' discussions relate to revised commercial terms and to re-initiating additional collaborations between faculty at TUM and Pieris. While an amended and restated license agreement has not yet been completed, we intend to enter into such an amendment. We recorded the probable expected impact of the amendment in research and development expense in 2018, which was an increase in our financial obligations associated with the TUM License of approximately $2.3 million for amounts that would be due in 2019 for 2018 and 2017 sub-licensing activities. This liability was paid in full in 2019. These discussions may also lead to an increase in our collaborative research activities with TUM.

Under the PD-1 In-License with Enumeral, we in-licensed intellectual property related to an Enumeral-generated antibody against PD-1 and are granted an option to in-license up to two additional antibodies against undisclosed targets. Under the terms of the PD-1 In-License, 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. On January 29, 2018, Enumeral filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the Bankruptcy Court. In connection with those proceedings, Enumeral transferred the intellectual property related to the PD-1 In-License to Acquisition Group, who have assumed the rights and obligations of Enumeral with respect to the PD-1 In-License.

As consideration, we are obliged to pay to Acquisition Group 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 Acquisition Group 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 Acquisition Group. Payment obligations terminate on a product-by-product and country-by-country basis on the later of 10 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 PD-1 In-License that cover the manufacture, use, offer for sale, sale or import of a product incorporating the Enumeral antibody.

In connection with our efforts to develop multispecific Anticalin-based proteins designed to engage immunomodulatory targets, during the second quarter of 2017, we entered into the Kelun Agreement. Under the Kelun Agreement, Kelun has granted to us a non-exclusive worldwide license (with the right to sublicense) under certain intellectual property owned or controlled by Kelun to research, develop, manufacture and commercialize bi- and multi- specific fusion proteins that include an antibody developed by Kelun specific for an undisclosed target and one or more Anticalin proteins.

In addition to the TUM License and the PD-1 In-License, we have other in-license agreements and 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 or the PD-1 In-License, the Kelun Agreement, or any future license agreement we may enter on which our business or drug candidates are dependent, TUM, Enumeral, Kelun, 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 and PD-1 In-License, our Anticalin drug therapies. Under the TUM License, 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 TUM License 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 PD-1 In-License, we can terminate the agreement upon 30 days' notice to Enumeral. Enumeral may terminate the PD-1 In-License 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.

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 could 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;
- how laws in the various jurisdictions, such as the USPTO or the European Patent Office, or the EPO, will change thus affecting our ability to obtain patents or maintain and enforce existing patents;
- 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 (for example, at the USPTO 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 or reverse engineer 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, adversely affecting 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. Inability to secure any 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, there may be instances when the prosecution and maintenance of issued patents and pending patent applications 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 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 distract our management and divert our limited time and resources. 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 may also be provoked or suggested 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.

Furthermore, 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, such as rendering issued patents unenforceable or terminating pending applications prematurely.

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, CMOs, 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.

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 built 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. However, 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 our 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 10 employees.

German employment termination law is regulated by various codes, in particular the *Kündigungsschutzgesetz*, or the 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 10 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 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 divert the attention of our executive officers 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 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.

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 *Gesetz über Arbeitnehmererfindungen*, or the German Act on Employees' Inventions, 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. Such disputes may be costly to defend and take up our management's time and efforts whether we prevail or not. 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.

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. Thus, the quoted price of our common stock is 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;
- the perception of the pharmaceutical and biotechnology industry by the public, legislatures, regulators and the investment community;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our drug candidates;
- significant lawsuits, including patent and stockholder class action litigation;
- 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 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 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. Furthermore, 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.

We have broad discretion in how we use our cash, cash equivalents and marketable securities, including the net proceeds from our collaborations, public and private securities offerings, and may not use these financial resources effectively, which could affect our results of operations and cause our stock price to decline.

Our management has considerable discretion in the application of our cash, cash equivalents and marketable securities, including the fees and milestone payments from our collaborations and the net proceeds of our securities offerings. We intend to use the cash, cash equivalents and marketable securities to advance our product candidates and for working capital and other general corporate purposes, which will include the hiring of additional personnel and capital expenditures. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the cash, cash equivalents and marketable securities. We may use the cash, cash equivalents and marketable securities for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the financial resources from our collaborations and securities offerings in a manner that does not produce income or that loses value.

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.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If only a few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively affected and there can be no assurance that analysts will provide favorable coverage. If securities or industry analysts who initiate coverage 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. As of December 31, 2019, we had six analysts covering our stock. We lack evidence of the potential benefits that coverage by additional analysts may provide.

We have material weaknesses in our internal controls over financial reporting, and we have had other material weaknesses in the past. 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. Section 404 of the Sarbanes-Oxley Act requires us to conduct an annual review and evaluation of our internal controls and to obtain attestations of the effectiveness of our internal controls over financial reporting by our independent registered public accounting firm.

If we cannot favorably assess the effectiveness of our internal controls over financial reporting, or if our independent registered public accounting 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.

As reported in this Annual Report on Form 10-K, we concluded that we had a material weakness in our internal controls over our information technology general controls ("ITGC") related to change and access management process, and as a result, internal controls related to substantially all underlying financial statement accounts and disclosures are ineffective. We also identified deficiencies in internal controls over our quarterly revenue recognition procedures, which were not operating effectively for a sufficient period of time in 2019, and certain controls related to the implementation of ASU No. 2014-09 “Revenue from Contracts with Customers” (Topic 606), or ASC 606, which, taken together, led us to determine that we had a material weakness in the revenue recognition process.

These material weaknesses create a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements may not be prevented or detected on a timely basis. No material financial statement misstatement was identified in relation to these material weaknesses in our internal control over financial reporting. Management, including our principal executive officer and principal financial officer, believes the consolidated financial statements included in this Annual Report on Form 10-K, fairly represent in all material respects our financial condition, results of operations and cash flows in accordance with U.S. GAAP. We cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future.

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 of the Securities Act, 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 of the Securities Act, sales of the securities of a former shell company, such as us, are not permitted unless at the time of a proposed sale, (i) we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act; and (ii) we 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 current reports on Form 8-K. 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. Furthermore, 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, 2019, a total of 55,212,437 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 our common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan, or issuable upon the conversion of our outstanding preferred stock or upon the exercise of our outstanding warrants, will be eligible for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and/or terms of such securities. 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 statements 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, we previously registered for resale shares of our common stock, which included all of the shares of our common stock issued in our private placements and in connection with the closing of the Acquisition. For example, in November 2019, we registered for resale 18,029,920 shares of common stock consisting of (w) 5,492,960 shares of common stock issued and outstanding at the time of filing such resale registration statement, (x) 3,522,000 shares of common stock issuable upon the conversion of 3,522 shares of our Series C Convertible Preferred Stock, par value $0.001 per share and (y) 9,014,960 shares of common stock issuable upon exercise of common stock purchase warrants. The resale registration statements permit 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 investors to sell shares of our common stock at times and prices that investors feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statements, we may continue to offer shares covered by the resale registration statements 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, in which we may 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 2019 Employee, Director and Consultant Equity Incentive Plan, or the Pieris 2019 Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 2,750,000 shares of our common stock reserved for issuance pursuant to the Pieris 2019 Plan, plus an additional 9,975,000 shares granted under the 2018, 2016 and 2014 Plans, including shares that expired or were canceled on or after July 31, 2019 under these plans and become available for grant under the Pieris 2019 Plan. As of December 31, 2019, we have granted options to purchase approximately 9,459,915 shares of our common stock. Pursuant to our 2018 Employee Stock Purchase Plan, we are authorized to sell 500,000 shares to our employees. 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 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."

We may incur significant costs from class action litigation due to our expected stock volatility.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts or the development efforts of future collaborators or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies.

This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, could result in substantial costs defending the lawsuit and diversion of the time, attention and resources of our Board of Directors and management, which could significantly harm our profitability and reputation.

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 we are not aware of any 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. Any return to our stockholders will therefore be limited to the appreciation of their stock.

We can issue and have issued shares of preferred stock, which may adversely affect the rights of holders of our common stock.

Our amended and restated Certificate of Incorporation authorizes us to issue up to 10,000,000 shares of preferred stock with designations, rights, and preferences determined from time-to-time by our Board of Directors. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an issuance of shares of preferred stock could:

- adversely affect the voting power of the holders of our common stock;
- make it more difficult for a third party to gain control of us;
- discourage bids for our common stock at a premium;
- limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or
- otherwise adversely affect the market price or our common stock.

We have in the past issued, and we may at any time in the future issue, shares of preferred stock. In connection with our June 2016 private placement, we issued 4,963 shares of our Series A convertible preferred stock to certain affiliates of Biotechnology Value Fund, L.P., or BVF, each share of which is convertible into 1,000 shares of our common stock, subject to

certain ownership restrictions. In January 2019, we entered into an exchange agreement with BVF, or the Exchange Agreement, to exchange 5,000,000 shares of our common stock previously held by BVF for 5,000 shares of our Series B convertible preferred stock, each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. In connection with our November 2019 private placement, we issued 3,522 shares of our Series C convertible preferred stock to certain affiliates of BVF each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. If the holders of our shares of preferred stock convert their shares into common stock, existing holders of our common stock will experience dilution.

Requirements associated with being a public company have increased our costs significantly and have diverted significant company resources and management attention.

We have only been subject to the reporting requirements of the Exchange Act and the other rules and regulations of the SEC since December 2014. As a public company listed on The Nasdaq Stock Market LLC, we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company.

We are subject to the reporting requirements of the Exchange Act, as well as various requirements imposed by the Sarbanes-Oxley Act, rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. The listing requirements of the Nasdaq Stock Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a codes of conduct.

Since we are no longer an “emerging growth company” as defined in the JOBS Act, we are no longer able to take advantage of certain exemptions from various reporting requirements that were previously available to us, but which were not available to other public companies that are not emerging growth companies. Accordingly, we are now required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, increased disclosure obligations regarding executive compensation in our periodic reports and proxy statements and the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, we will incur greater expenses associated with such reporting requirements. These expenses would further increase if we ceased to be a “smaller reporting company.”

Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Having availed ourselves of scaled disclosure available to smaller reporting companies, we cannot be certain if such reduced disclosure will make our common stock less attractive to investors.

Under Rule 12b-2 of the Exchange Act, a "smaller reporting company" is a company that is 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, according to the amended definition effective September 10, 2018, had a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year. Smaller reporting companies are permitted to provide simplified executive compensation disclosure in their filings; and they 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. We qualify as a smaller reporting company. For as long as we continue to be 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. Decreased disclosure in our SEC filings as a result of our having availed ourselves of scaled disclosure 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

During 2019, we leased approximately 19,000 square feet of office and laboratory space in Freising, Germany under four agreements, including three leases for space on three floors of the same building and a letter agreement for additional conference room space within the building. We extended each lease through March 31, 2020, at which point our lease obligations terminate for this location.

In October 2018, Pieris GmbH entered into a lease initially comprising of approximately 96,400 square feet of mixed laboratory and office space in Hallbergmoos, Germany, which become our location for all German operations in February 2020. This agreement, or the Lease Agreement, provides for an initial term of 150 months, commencing on the date the lessor first delivers the leased property to Pieris GmbH as agreed under the Lease Agreement, which occurred in February 2020. Pieris GmbH and the lessor are each entitled to terminate the Lease Agreement for due cause.

We lease 3,950 square feet of office space in Boston, Massachusetts under a sublease, or the Sublease, that houses our executive offices, clinical operations, and other operational functions. The Sublease expires on February 27, 2022 or such earlier date pursuant to the termination provisions of the Sublease. 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 listed on The Nasdaq Stock Market LLC under the symbol "PIRS" and on June 30, 2015 our common stock began trading on The Nasdaq Capital Market.

Stockholders

As of March 9, 2019, there were 49 and 4 stockholders of record of our common stock and preferred stock, respectively. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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 on Form 10-K, 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 unique and transformative ways. Our clinical pipeline includes an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma, and an immuno-oncology (IO) bispecific targeting HER2 and 4-1BB. Proprietary to us, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies. Our development programs include:

- *PRS-060/AZD1402*, our lead respiratory program partnered with AstraZeneca, a drug candidate that antagonizes IL-4Rα, thereby inhibiting IL-4 and IL-13, two cytokines known to be key mediators in the inflammatory cascade that drive the pathogenesis of asthma and other inflammatory diseases. We are sponsoring the phase 1 studies of PRS-060/AZD1402 with and AstraZeneca is funding the costs. AstraZeneca will conduct and fund the phase 2a study of the drug candidate, after which we will have separate options to co-develop and co-commercialize PRS-060/AZD1402 in the United States.

- We are developing additional respiratory drug candidates beyond PRS-060/AZD1402, within and outside of the AstraZeneca alliance. We have initiated three discovery-stage respiratory programs in our alliance with AstraZeneca, the targets and disease areas for which are undisclosed. AstraZeneca may initiate one additional program within the alliance, for a total of four programs beyond PRS-060/AZD1402. We retain co-development and co-commercialization rights to two out of the four programs beyond PRS-060/AZ1402. We also continue to advance several discovery-stage respiratory programs outside of the AstraZeneca collaboration.

- *PRS-343*, our lead IO program, is a fusion protein, comprising a HER2-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins. PRS-343 is designed to drive tumor localized T-cell activation through tumor-targeted drug clustering mediated by HER2 expressed on tumor cells. This program was the first bispecific T-cell co-stimulatory agonist to enter clinical development.

- We are also developing additional IO drug candidates that are multispecific Anticalin-based fusion proteins designed to engage immunomodulatory targets, comprising a variety of multifunctional biotherapeutics, including PRS-344, a bispecific antibody-Anticalin fusion protein comprising an PD-L1-targeting antibody genetically fused to Anticalin proteins specific for 4-1BB. PRS-344 is being developed as part of our IO collaboration with Servier.

Our programs are in varying stages:

- PRS-060/AZD1402 was tested in a nebulized formulation in 54 healthy volunteers at nominal dose levels ranging from 0.25 mg to 400 mg in a phase 1 SAD study. Data from that study were presented at the American Thoracic Society International Conference in May 2019 showing that PRS-060/AZD1402 was well tolerated when given as a single inhaled or intravenous doses to healthy volunteers and there was systemic target engagement (as measured by pSTAT6 inhibition). We presented interim data from the ongoing PRS-060/AZD1402 phase 1 MAD study at the European Respiratory Society International Congress in October 2019 and reported that PRS-060/AZD1402 was safe and well-tolerated at all doses, led to a statistically significant reduction in FeNO, a validated biomarker for eosinophilic airway inflammation, and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO (≥ 35ppb). In that study, during the treatment period, 30 patients were randomized to receive delivered doses of PRS-060/AZD1402 ranging from 2 mg to 60 mg (5 mg to 150 mg administered through a nebulizer (nominal dose)) twice daily for nine consecutive days and one final dose on the 10th day, and 12 patients were randomized to receive placebo at the same intervals. Statistically significant and pronounced inhibition of FeNO relative to placebo was observed at all doses. When comparing the 20 mg PRS-060/AZD1402 powered cohort (n=12) to placebo, the primary statistical analysis using the emax model demonstrated a 36% relative reduction in FeNO (p-value <0.0001). Systemic target engagement was dose-dependent and closely aligned with systemic exposure of the drug, consistent with results of the phase 1 SAD study. No systemic target engagement and minimal systemic exposure was observed at the 2 mg dose, suggesting that local target engagement by the drug may be sufficient to reduce airway inflammation, as evidenced by FeNO reduction at that 2 mg dose level. Following these reported results, we and AstraZeneca are preparing to move into a phase 2a study in moderate-to-severe asthmatics in the second half of 2020.

- We presented interim data from our phase 1 dose escalation study at the SITC annual meeting on November 9, 2019. We reported that PRS-343 was well tolerated and had a favorable safety profile at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types and showed a potent increase in CD8+ T-cell numbers in the tumor microenvironment of responders, indicative of 4-1BB agonism on T-cells. Pieris continues to enroll patients in that study at higher dose cohorts and plans to initiate the next stage of clinical development in gastric cancer this year. We also continue to enroll the dose-escalation phase 1 study of PRS-343 in combination with atezolizumab and reported initial data from the study at our R&D day on November 19, 2019 in New York.

- For our other IO drug candidates and programs, we are conducting activities relating to candidate identification, optimization and preclinical evaluation. We achieved two preclinical milestones in connection with the PRS-344 program, one in December 2018 and another in February 2019, triggering two milestone payments from Servier, and intend to file an IND for the drug candidate in the first half of 2020. We also executed our option to opt-into co-development and United States commercialization of PRS-344 during the first quarter of 2019. In September 2019, Servier notified us of its decision to discontinue co-development of PRS-332, a PD-1-LAG-3 bispecific for strategic reasons. We do not presently intend to continue development of PRS-332 but retain full rights to advance the development and commercialization of the product on a world-wide basis. Servier's termination of the co-development of the PRS-332 program does not impact the remainder of the Pieris-Servier alliance and the parties continue to advance PRS-344 through IND-enabling activities. The Pieris-Servier alliance includes three additional programs beyond PRS-344, all of which are in active preclinical development.

Our core Anticalin technology and platform were developed in Germany and we have collaborations with major multi-national pharmaceutical companies. In particular, we have an alliance with AstraZeneca to treat respiratory diseases and partnerships with Servier and Seattle Genetics, both in IO.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities and have incurred significant net losses. For the years ended December 31, 2019 and 2018, we reported net losses of $25.5 million and $26.8 million, respectively. As of December 31, 2019, we had an accumulated deficit of $174.2 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, 2019 and 2018 were from license and collaboration agreements with our partners.

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. At each period end, we remeasure assets and liabilities to the functional currency of that entity (for example, U.S. dollar payables recorded by Pieris Pharmaceuticals GmbH). Remeasurement gains and losses are recorded in the statement of operations line item 'Other income (expense), net'. 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 weighted average rate during the period. Equity transactions are translated using historical exchange rates. All adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive loss.

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 AstraZeneca, Servier, and Seattle Genetics.

The revenues from AstraZeneca, Servier, and Seattle Genetics have been comprised primarily of upfront payments, research and development services, and milestone payments. For additional information about our revenue recognition policy, see “Note 2-Summary of Significant Accounting Policies”.

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 expenses will be incurred. Our current development plans focus on the following programs: our lead respiratory program, PRS-060/AZD1402 and our other respiratory programs, our IO programs, currently comprised of PRS-343 as well as multiple additional proprietary and partnered programs, including PRS-344. 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 personnel-related costs (salaries, employee benefits, equity compensation, and other costs), materials and supplies, facilities and maintenance costs attributable to research and development functions; and

- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing and related testing, and clinical trial activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, 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, along with facility and maintenance costs attributable to general and administrative functions.

Results of Operations

Comparison of Years Ended December 31, 2019 and December 31, 2018

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018
Revenues	$ 46,279	$ 29,101
Research and development expenses	54,996	41,490
General and administrative expenses	18,440	18,442
Total operating expenses	73,436	59,932
Interest income	1,714	1,962
Other (expense) income , net	(26)	1,803
Loss before income taxes	(25,469)	(27,066)
Benefit for income tax	—	(312)
Net loss	$ (25,469)	$ (26,754)

Revenues

The following table provides a comparison of revenues for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,		
	2019	2018	Increase/(Decrease)
Revenue from contracts with customers	$ 43,646	$ 27,248	$ 16,398
Collaboration revenue	2,633	1,762	$ 871
Other	—	91	$ (91)
Total Revenue	$ 46,279	$ 29,101	$ 17,178

- The $16.4 million increase in revenue from contracts with customers for the year ended December 31, 2019 compared to the year ended December 31, 2018 primarily relates to higher amounts of Servier revenue recorded upon termination of the co-development of PRS-332 by Servier for strategic reasons, higher revenue for AstraZeneca due to the termination of certain performance obligations determined at the origination of the agreement, and recognition of previously-deferred revenue for ASKA upon delivery of the final clinical report. These increases were partially offset by lower activity levels with respect to our collaboration agreement with Seattle Genetics and revenue recognized upon termination of our agreement with Roche in 2018.

- The $0.9 million increase in collaboration revenues in the year ended December 31, 2019 compared to the year ended December 31, 2018 relates to increased research and development activities under our collaboration with Servier.

Research and Development Expenses

The following table provides a comparison of the research and development expenses for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,		
	2019	2018	Increase/(Decrease)
Immuno-oncology	$ 19,669	$ 13,654	$ 6,015
Respiratory	11,634	8,632	$ 3,002
Anemia	177	1,664	$ (1,487)
Other R&D activities	23,516	17,540	$ 5,976
Total	$ 54,996	$ 41,490	$ 13,506

- the $6.0 million increase in our immuno-oncology program spending period-over-period is due primarily to an increase in clinical trials costs incurred for PRS-343 and drug product manufacturing for PRS-343, PRS-344 and other proprietary programs;

- the $3.0 million increase for our respiratory programs period-over-period is due primarily to increases to our ongoing CMC costs incurred for phase 2a readiness for PRS-060/AZD1402 offset by slightly lower clinical costs as the phase 1 SAD study that was completed earlier in 2019. We also incurred higher pre-clinical and lab supply expenses as we initiated and were working on more proprietary and partnered respiratory programs in 2019 as compared to 2018;

- the $1.5 million decrease for our anemia program, PRS-080, period-over-period is mainly due to lower clinical costs as the phase 2a study ended in 2019 compared to being active during the same period in 2018; and

- the $6.0 million increase in other research and development activities expenses is mainly due to higher personnel expenses, including bonus and stock compensation, due to an overall increase in headcount; an increase in recruiting costs; and an increase in allocated facility costs due to higher non-cash rent charges for the new Hallbergmoos facility that we took occupancy of in February 2020.

General and Administrative Expenses

General and administrative expenses were $18.4 million for both fiscal years ended December 31, 2019 and December 31, 2018. The period over period consistency is due to decreases in investor relations, third party legal and recruiting as we have better leveraged internal resources, offset completely by increases in audit and tax due to new accounting regulations and internal control requirements and hardware and software costs to support growth and efficiency.

Non-operating income (expense), net

Our non-operating income was $1.7 million for the year ended December 31, 2019 as compared to a $3.8 million for the year ended December 31, 2018. This decrease is due to lower interest income as a result of lower invested amounts throughout 2019 and a strengthening of the U.S. dollar against the euro for the majority of 2019. In 2018, a larger foreign currency gain was recorded in U.S. dollars due to a large receivable related to the Seattle Genetics collaboration.

Income tax benefit (expense)

We did not record an income tax benefit or expense for the year ended December 31, 2019. For the year ended December 31, 2018 we recorded an income tax benefit from continuing operations of $0.3 million related to an intraperiod tax benefit due to taxable gains in other comprehensive income.

Liquidity and Capital Resources

Through December 31, 2019, we have funded our operations with $425.5 million of cash that has been obtained from the following main sources: $202.7 million from sales of equity; $202.1 million in total payments received under license and collaboration agreements, including $34.5 million for research and development services costs received from our collaboration partners; $14.2 million from government grants and $6.5 million from loans.

As of December 31, 2019, we had a total of $104.2 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the years ended December 31, 2019 and 2018, respectively, and have a total accumulated deficit of $174.2 million as of December 31, 2019.

We have several research and development programs underway in varying stages of development and we expect they will continue to require increasing amounts of cash for development, conducting clinical trials, and testing and manufacturing of product material. We expect cash necessary to fund operations will increase significantly over the next several years as we continue to conduct these activities necessary to pursue governmental regulatory approval of clinical-stage programs and our other product candidates.

The following table provides a summary of operating, investing, and financing cash flows for the years ended December 31, 2019 and 2018 respectively (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2018
Net cash (used in) operating activities	$ (52,467)	$ (1,066)
Net cash provided by (used in) investing activities	9,838	(8,875)
Net cash provided by financing activities	32,166	48,511

Net cash used in operating activities of $52.5 million for the year ended December 31, 2019 is comprised principally of operating expenses of $65.6 million, net of non-cash items, offset by aggregate receipts of $13.7 million from AstraZeneca, Servier, and Seattle Genetics and an increase in net working capital of $0.9 million. Net cash used in operating activities of $1.1 million for the year ended December 31, 2018 is comprised principally of operating expenses of $50.6 million, net of non-cash items, offset by aggregate receipts of $50.9 million from AstraZeneca, Servier, and Seattle Genetics and an increase in net working capital of $0.4 million.

The change in net cash provided by investing activities for the year ended December 31, 2019 compared to net cash used in the year ended December 31, 2018 is mainly attributable to less investment purchases than investment maturities in the current year compared to 2018.

Financing activities for the year ended December 31, 2019 were $32.2 million due primarily to proceeds from the 2019 private placement (described below), along with exercises of options and warrants and proceeds from the employee stock purchase plan. Net cash provided by financing activities in 2018 consisted of $47.2 million in proceeds due to the issuance of common stock under our February 2018 underwritten public offering along with $1.3 million of proceeds from the exercise of warrants and stock options for the year ended December 31, 2018.

In August 2019, the Company entered into a sale agreement pursuant to which the Company may offer and sell shares of its common stock, from time to time, up to an aggregate gross sales proceeds of $50.0 million through an “at the market offering” program under a shelf registration statement on Form S-3. To date, the Company has not sold any shares under this agreement.

In November 2019, 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 PIPE, consisted of 9,014,960 units, at a price of $3.55 per unit, for gross proceeds of approximately $32.0 million, and net proceeds to the Company of approximately $31.0 million, after deducting placement agent fees and estimated offering expenses payable by us. Each unit consists of (i) one share of our common stock or 0.001 shares of non-voting Series C convertible preferred stock, and (ii) one immediately-exercisable warrant to purchase one share of our common stock with an exercise price of $7.10.

We expect that our existing cash, cash equivalents, and investments will enable us to fund our operational and capital expenditure requirements for at least twelve months from the issuance date of these financial statements. Any 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.

Due to the often-volatile nature of the financial markets, equity and debt financing(s) may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our core clinical-stage programs including PRS-343 and PRS-060/AZD1402 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 space in Boston, Massachusetts. In August 2015, we entered into a sublease to lease approximately 3,950 square feet. The sublease expires on February 27, 2022 or such earlier date pursuant to the termination provisions of the sublease.

We also lease approximately 19,000 square feet of office and laboratory space in Freising, Germany under four agreements, the Freising Leases, including three leases for space on three floors of the same building and a letter agreement for additional conference room space within the building. The Freising Leases all terminate on March 31, 2020.

In October 2018, Pieris GmbH entered into a new lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. Pieris GmbH moved its operations, formerly conducted in Freising, Germany, to the Hallbergmoos facility in February 2020.

Under the Hallbergmoos Lease, Pieris GmbH will rent approximately 105,000 square feet, of which approximately 96,400 square feet were delivered by the lessor in February 2020 and approximately 8,600 square feet is expected to be delivered by the lessor by May 2020. An additional approximately 22,300 square feet is expected to be delivered by the lessor by October 2024. Pieris GmbH has a first right of refusal to lease an additional approximate 13,400 square feet.

The Hallbergmoos Lease provides for an initial rental term of 12.5 years which commenced on February 2020. Pieris GmbH also has an option to extend the Hallbergmoos Lease for two additional 60-month periods. We are not reasonably certain to exercise the option to extend the lease expiration beyond its current expiration date. Pieris GmbH may sublease space within the leased property with lessor's consent, which may not be unreasonably withheld.

Monthly base rent for the initial 105,000 square feet of the leased property, including parking spaces, will total approximately $0.2 million per month, which amount shall be adjusted starting on the second anniversary of the commencement date by an amount equal to the German consumer price index. In addition to the base rent, Pieris GmbH is also responsible for certain administrative and operational costs in accordance with the Hallbergmoos Lease. Pieris GmbH provided a security deposit of $0.8 million as of December 31, 2018. The Company will serve as a guarantor for the Hallbergmoos Lease.

Pieris GmbH and the lessor are each entitled to terminate the Hallbergmoos Lease for due cause. Specifically, the lessor may terminate for Pieris GmbH's default on rent payments beyond certain amounts, noncompliance with major obligations under the Hallbergmoos Lease, and certain bankruptcy and insolvency events.

The maturities of our operating lease liabilities and minimum lease payments as of December 31, 2019 were as follows (in thousands):

	Total
2020	$ 2,317
2021	2,418
2022	2,249
2023	2,214
2024	2,214
Thereafter	16,790
Total undiscounted lease payments	28,202
Less: present value adjustment	(11,985)
Present value of lease liabilities	$ 16,217

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined under applicable SEC rules.

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.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements, 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

Effective January 1, 2019, we adopted ASC 606. The standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that we expect to receive for those goods or services. The standard allows for two transition methods -- full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. We elected the modified retrospective approach and applied it to contracts not completed at the date of adoption. Therefore, comparative prior periods have not been adjusted. The reported results for 2019 reflect the application of ASC 606 guidance while the reported results for 2018 were prepared under the guidance of FASB ASC Topic 605, *Revenue Recognition*, or ASC 605. Furthermore, we adopted the contract modification practical expedient set forth in ASC 606 and will reflect the aggregate effect of all modifications that occurred before January 1, 2019 when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price to the satisfied and unsatisfied performance obligations.

Collaborative Arrangements

We consider the nature and contractual terms of an arrangement and assess whether the arrangement involves a joint operating activity pursuant to which we are an active participant and are exposed to significant risks and rewards with respect to the

arrangement. If we are an active participant and are exposed to the significant risks and rewards with respect to the arrangement, we account for these arrangements pursuant to ASC 808, *Collaborative Arrangements*, or ASC 808, and apply a systematic and rational approach to recognize revenue. We classify payments received as revenue and payments made as a reduction of revenue in the period in which they are earned.

Revenue from Contracts with Customers

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled in exchange for these goods and services. To achieve this core principle, we apply the following five steps: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied.

We evaluate all promised goods and services within a customer contract and determines which of such goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

Licensing arrangements are analyzed to determine whether the promised goods or services, which often include licenses, research and development services and governance committee services, are distinct or whether they must be accounted for as part of a combined performance obligation. If the license is considered not to be distinct, the license would then be combined with other promised goods or services as a combined performance obligation. If we are involved in a governance committee, we assess whether our involvement constitutes a separate performance obligation. When governance committee services are determined to be separate performance obligations, we determine the fair value to be allocated to this promised service.

Certain contracts contain optional and additional items, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. An option that is considered a material right is accounted for as a separate performance obligation.

The transaction price is determined based on the consideration to which we will be entitled in exchange for transferring goods and services to the customer. A contract may contain variable consideration, including potential payments for both milestone and research and development services. For certain potential milestone payments, we estimate the amount of variable consideration by using the most likely amount method. In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period we re-evaluate the probability of achievement of such variable consideration and any related constraints. We will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. For potential research and development service payments, we estimate the amount of variable consideration by using the expected value method, including any approved budget updates arising from additional research or development services.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price among the performance obligations on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

We allocate the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. We must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amount we would expect to receive for each performance obligation.

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price

basis. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete its performance obligations under an arrangement.

For performance obligations consisting of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non- refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

Milestones and Royalties

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, including regulatory approval. Sales milestones are 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.

There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of our technology. We have thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur. For revenues from research and development milestones, payments will be recognized consistent with the recognition pattern of the performance obligation to which they relate.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Commercial milestones and sales royalties are determined by sales or usage-based thresholds and will be accounted for under the royalty recognition constraint as constrained variable consideration.

Contract Balances

We recognize a contract asset when we transfer goods or services to a customer before the customer pays consideration or before payment is due, excluding any amounts presented as a receivable (i.e., accounts receivable). A contract asset is an entity’s right to consideration in exchange for goods or services that the entity has transferred to a customer. The contract liabilities (i.e., deferred revenue) primarily relate to contracts where we have received payment but has not yet satisfied the related performance obligations.

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. Nonrefundable advance payments for research and development goods or services to be received in the future are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. 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

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 our net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce our 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 extent to which our deferred tax assets may be realized 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 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.

Smaller Reporting Company Status

Currently, we qualify as a smaller reporting company.

As a smaller reporting company, we are eligible and have taken advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for this classification, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures, and reduced financial statement disclosure in registration statements and in annual reports on Form 10-K, which only requires two years of audited financial statements rather than the three years of audited financial statements that are required for other public companies. For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of this classification.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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-3 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) of 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. Our 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 Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting and disclosure controls and procedures as of December 31, 2019. 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, 2019, our disclosure controls and procedures and internal control over financial reporting were not effective, as described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of a company’s annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

In connection with the preparation of our financial statements for the year ended December 31, 2019, we identified a material weakness in internal controls over our information technology general controls ("ITGC") related to change and access management process, and as a result, internal controls related to substantially all underlying financial statement accounts and disclosures are ineffective. We also identified deficiencies in internal controls over our quarterly revenue recognition procedures in that they were not operating effectively for a sufficient period of time in 2019 and certain controls related to the implementation of ASU No. 2014-09 “Revenue from Contracts with Customers” (Topic 606), or ASC 606. which, taken together, led us to determine that we had a material weakness in the revenue recognition process.

These material weaknesses created a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements may not be prevented or detected on a timely basis. No material financial statement misstatements were identified in relation to these material weaknesses in our internal control over financial reporting.

Management intends to implement remediation plans to address the control deficiencies that led to these material weaknesses, and will continue to evaluate and take actions to improve the company's internal control over financial reporting. Our remediation plan with respect to our controls over ITGC will include reevaluating our risk assessment and IT control environment within the finance department, developing an IT policy with a clear description on how the controls are designed to operate, and establishing or enhancing controls over system access, administration, and system changes. Our remediation plan with respect to our controls over our revenue recognition process includes, beginning with the first quarter of 2020, performing and retaining sufficient documentation of our operating controls. Our remediation plan with respect to ASC 606 implementation will involve instances of control execution with respect to any new and existing collaboration agreements and the allocation of up-front consideration to the identified performance obligations.

Remediation of Material Weakness from 2018

As previously disclosed, in connection with the preparation of our financial statements for the year ended December 31, 2018, we concluded that we had a material weakness relating to our income tax provision process, including the evaluation of any changes resulting from the recent tax laws. To remediate the material weakness identified, we performed the following actions during 2019:

- Developed and documented formal policies regarding the income tax provision process, including the identification of key controls and necessary steps by which management can evaluate the use of third party specialists.
- Developed and utilized a detailed checklist to identify significant transactions and/or events that may require further evaluation by tax advisors or tax specialists as part of the quarterly and annual tax provision process.
- Ensured that management's oversight of external advisors was appropriate, including that adequate resources were available and that sufficient preparation and review activities occurred when calculating the quarterly and annual tax provision. This included the ability to engage and involve certain tax specialists to assist in the assessment and evaluation of certain tax matters, as needed.
- Prepared documentation that was sufficiently reviewed by our external tax advisors and by finance management that addressed all significant tax matters identified for each reporting period.

As the implementation of the enhanced policies, procedures and controls have functioned effectively for multiple quarters, we concluded that we have remediated the aggregated material weakness previously disclosed from 2018.

Notwithstanding the new material weaknesses identified as of December 31, 2019, we have concluded that the financial statements and other financial information included in this Annual Report on Form 10-K, fairly present 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 for material weaknesses and remediation activities described 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 fourth quarter of 2019 have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Registered Public Accounting Firm

The effectiveness of our internal controls over financial reporting as of December 31, 2019 has been audited by our independent registered accounting firm, Ernst & Young LLP, as stated in their attestation report.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Pieris Pharmaceuticals, Inc.:

Opinion on Internal Control over Financial Reporting

We have audited Pieris Pharmaceutical, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weaknesses described below on the achievement of the objectives of the control criteria, Pieris Pharmaceuticals, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Management has identified material weaknesses in accounting for revenue and over information technology general controls and as a result, internal controls related to substantially all underlying financial statement accounts and disclosures are ineffective.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and December 30, 2018, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2019 consolidated financial statements, and this report does not affect our report dated March 13, 2020, which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Evaluation of Disclosure Controls and Procedures in Item 9a. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
Boston, MA
March 13, 2020

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2019.

Item 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2019.

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

The information required by this Item 12 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2019.

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

The information required by this Item 13 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2019.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2019.

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	Certificate of Designation of Series B Convertible Preferred Stock		Form 8-K (Exhibit 3.1)	February 4, 2019	001-37471
3.4	Certificate of Designation of Series C Convertible Preferred Stock		Form 8-K (Exhibit 3.1)	November 4, 2019	001-37471
3.5	Amended and Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.2)	December 18, 2014	333-190728
3.6	Amendment to the Amended and Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.1)	September 3, 2019	001-37471
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
4.3	Description of Registered Securities	*			
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	#	Form 10-K (Exhibit 10.4)	March 30, 2017	001-37471
10.5	2018 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	July 26, 2018	001-37471
10.6	Form of Stock Option Award Agreement under the Registrant's 2018 Employee, Director and Consultant Equity Incentive Plan	#	Form S-8 (Exhibit 10.2)	August 9, 2018	333-226733

10.7	2018 Employee Stock Purchase Plan	#	Form 8-K (Exhibit 10.2)	July 26, 2018	001-37471
10.8	2019 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	July 31, 2019	001-37471
10.9	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, 2015	333-190728
10.10	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
10.11	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
10.12	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		Form 10-K (Exhibit 10.14)	March 30, 2017	001-37471
10.13	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	±	Form 10-K/A (Exhibit 10.15)	April 26, 2018	001-37471
10.14	Non-Exclusive Anticalin Platform Technology License Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017	±	Form 10-K/A (Exhibit 10.16)	April 26, 2018	001-37471
10.15	First Amendment to the License and Collaboration Agreement by and between Les Laboratoires Servier, Institut de Recherches Internationales Servier, Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH, effective as of June 16, 2017	±	Form 10-Q/A (Exhibit 10.4)	April 26, 2018	001-37471
10.16	Letter Amendment to the License and Collaboration Agreement by and between Les Laboratoires Servier, Institut de Recherches Internationales Servier, Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH, effective as of January 3, 2020	*+			
10.17	Exclusive Option Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH and ASKA Pharmaceutical Co., Ltd., dated as of February 27, 2017	±	Form 10-Q/A (Exhibit 10.3)	April 26, 2018	001-37471
10.18	License & Collaboration Agreement by and between Pieris Pharmaceuticals Inc., Pieris Pharmaceuticals GmbH & Pieris Australia Pty. Limited and AstraZeneca AB, dated as of May 2, 2017	±	Form 10-Q/A (Exhibit 10.1)	April 26, 2018	001-37471

10.19	Non-Exclusive Anticalin® Platform Technology License Agreement, by and between Pieris Pharmaceuticals Inc., Pieris Pharmaceuticals GmbH and Pieris Australia Pty. Limited and AstraZeneca AB, dated as of May 2, 2017	±	Form 10-Q/A (Exhibit 10.2)	April 26, 2018	001-37471
10.20	License and Collaboration Agreement by and among the Registrant, Pieris GmbH and Seattle Genetics, Inc., dated February 8, 2018	±	Form 10-Q (Exhibit 10.1)	May 10, 2018	001-37471
10.21	Non-Exclusive Anticalin Platform Technology License Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH and Seattle Genetics, Inc., dated February 8, 2018	±	Form 10-Q (Exhibit 10.2)	May 10, 2018	001-37471
10.22	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
10.23	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
10.24	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 13, 2015	001-37471
10.25	Letter Agreement by and between the Registrant and Louis A. Matis, M.D., dated as of January 8, 2020	*#			
10.26	Non-Employee Director Compensation Policy, as amended	*#			
10.27	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
10.28	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 13, 2015	001-37471
10.29	Subtenant Recognition and Attornment Agreement, by and among Pieris Pharmaceuticals, Inc., 225 State Street, LLC, and Berenberg Capital Markets LLC, dated as of May 31, 2019		Form 10-Q (Exhibit 10.29.1)	August 9, 2019	001-37471
10.30	Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated October 24, 2018		Form 10-K (Exhibit 10.30)	March 18, 2019	001-37471
10.31	Amendment No. 1 to Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated May 21, 2019 (English translation)	*			
10.32	Amendment No. 2 to Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated February 13, 2020 (English translation)	*			
10.33	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

10.34	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
10.35	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
10.36	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
10.37	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
10.38	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
10.39	Securities Purchase Agreement, dated November 2, 2019, by and among the Company and the Investors named therein		Form 8-K (Exhibit 10.1)	November 4, 2019	001-37471
10.40	Registration Rights Agreement, dated November 2, 2019, by and among the Company and the Investors named therein		Form 8-K (Exhibit 10.3)	November 4, 2019	001-37471
10.41	Form of Warrant to purchase Common Stock, dated November 2, 2019, issued by the Registrant		Form 8-K (Exhibit 10.2)	November 4, 2019	001-37471
10.42	Exchange Agreement, dated January 30, 2019, by and among the Registrant and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., and Biotechnology Value Trading Fund OS, L.P.		Form 8-K (Exhibit 10.1)	February 4, 2019	001-37471
10.43	Open Market Sale Agreement, dated as of August 9, 2019, by and between Pieris Pharmaceuticals, Inc. and Jefferies LLC		Form 10-Q (Exhibit 10.1)	August 9, 2019	001-37471
10.44	Managing Director Services Agreement by and between Pieris Pharmaceuticals GmbH and Hitto Kaufmann, Ph.D., dated as of August 30, 2019	#	Form 10-Q (Exhibit 10.2)	November 12, 2019	001-37471
10.45	Non-Qualified Stock Option Agreement by and between the Registrant and Hitto Kaufmann, Ph.D., dated as of August 30, 2019	#	Form 10-Q (Exhibit 10.3)	November 12, 2019	001-37471
14.1	Corporate Code of Ethics and Conduct and Whistleblower Policy	*			
21.1	List of Subsidiaries	*			
23.1	Consent of Ernst & Young LLP	*			
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 Thomas Bures, Vice President of Finance, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*			

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 Thomas Bures, Vice President of Finance, 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.
+	Portions of the exhibit are omitted pursuant to Regulation S-K Item 601(b)(10)(iv). Copies of the unredacted exhibit will be furnished to the SEC upon request.
#	Indicates a management contract or compensatory plan

Item 16. FORM 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.

March 13, 2020

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 13, 2020
/s/ Thomas Bures Thomas Bures	Vice President, Finance and Treasurer *(Principal Financial and Accounting Officer)*	March 13, 2020
/s/ James Geraghty James Geraghty	Chairman of the Board of Directors	March 13, 2020
/s/ Jean-Pierre Bizzari, M.D. Jean-Pierre Bizzari, M.D.	Director	March 13, 2020
/s/ Michael Richman Michael Richman	Director	March 13, 2020
/s/ Maya R. Said, Sc.D. Maya R. Said, Sc.D.	Director	March 13, 2020
/s/ Peter Kiener, D.Phil. Peter Kiener, D.Phil.	Director	March 13, 2020
/s/ Christopher Kiritsy Christopher Kiritsy	Director	March 13, 2020
/s/ Ann Barbier, M.D., Ph.D. Ann Barbier, M.D., Ph.D.	Director	March 13, 2020
/s/ Matthew L. Sherman, M.D. Matthew L. Sherman, M.D.	Director	March 13, 2020

PIERIS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Pieris Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pieris Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 13, 2020 expressed an adverse opinion thereon.

Adoption of New Accounting Standards

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and related amendments.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02, Leases (Topic 842), and related amendments.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Boston, Massachusetts

March 13, 2020

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 62,260	$ 74,867
Short term investments	41,894	53,240
Accounts receivable	6,787	2,701
Prepaid expenses and other current assets	4,072	4,574
Total current assets	115,013	135,382
Property and equipment, net	19,502	5,049
Operating lease right-of-use assets	3,436	—
Other non-current assets	3,146	910
Total assets	$ 141,097	$ 141,341
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,803	$ 3,350
Accrued expenses and other current liabilities	9,944	9,114
Deferred revenues, current portion	11,256	35,612
Total current liabilities	27,003	48,076
Deferred revenue, net of current portion	47,258	53,303
Operating lease liabilities	15,484	—
Other long-term liabilities	—	27
Total liabilities	89,745	101,406
Stockholders' equity:		
Preferred stock, $0.001 par value per share, 10,000,000 shares authorized at December 31, 2019 and 2018, respectively		
Series A Convertible, 2,907 shares issued and outstanding at December 31, 2019 and 2018, respectively	—	—
Series B Convertible, 5,000 and 0 shares issued and outstanding at December 31, 2019 and 2018, respectively.	—	—
Series C Convertible, 3,522 and 0 shares issued and outstanding at December 31, 2019 and 2018, respectively.	—	—
Common stock, $0.001 par value per share, 300,000,000 shares authorized and 55,212,437 and 54,151,219 issued and outstanding at December 31, 2019 and 2018, respectively	55	54
Additional paid-in capital	227,468	189,929
Accumulated other comprehensive loss	(1,995)	(2,982)
Accumulated deficit	(174,176)	(147,066)
Total stockholders' equity	51,352	39,935
Total liabilities and stockholders' equity	$ 141,097	$ 141,341

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

	Years Ended December 31,	
	2019	**2018**
Revenue	$ 46,279	$ 29,101
Operating expenses		
Research and development	54,996	41,490
General and administrative	18,440	18,442
Total operating expenses	73,436	59,932
Loss from operations	(27,157)	(30,831)
Interest income	1,714	1,962
Other (expense) income, net	(26)	1,803
Loss before income taxes	(25,469)	(27,066)
Benefit for income tax	—	(312)
Net loss	(25,469)	(26,754)
Foreign currency translation	973	1,196
Unrealized gain on available-for-sale securities, net of taxes of $0 and $164, respectively	14	517
Comprehensive loss	$ (24,482)	$ (25,041)
Reconciliation of net loss to net loss attributable to common stockholders:		
Net loss	$ (25,469)	$ (26,754)
Accretion of Series C convertible preferred stock	(2,830)	—
Net loss attributable to common stockholders	(28,299)	(26,754)
Net loss per share:		
Basic and diluted	$ (0.56)	$ (0.50)
Weighted average number of common shares outstanding used in net loss per share attributable to common stockholders		
Basic and diluted	50,625	53,081

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands)

	Convertible series A preferred shares		Convertible series B preferred shares		Convertible series C 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	No. of shares	Share capital	No. of shares	Share capital				
Balance as of January 1, 2018	5	—	—	—	—	—	45,017	45	136,484	(4,695)	(120,312)	11,522
Net loss	—	—	—	—	—	—	—	—	—	—	(26,754)	(26,754)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	1,196	—	1,196
Unrealized gain on investments, net of $164 tax provision	—	—	—	—	—	—	—	—	—	517	—	517
Stock based compensation expense	—	—	—	—	—	—	—	—	4,943	—	—	4,943
Issuance of common stock resulting from exercise of stock options	—	—	—	—	—	—	596	1	985	—	—	986
Issuance of common stock resulting from exercise of warrants	—	—	—	—	—	—	157	—	314	—	—	314
Issuance of common stock net $3,374 in offering costs	—		—	—	—	—	6,325	6	47,205	—	—	47,211
Preferred stock conversion	(2)	—	—	—	—	—	2,056	2	(2)	—	—	—
Balance as of December 31, 2018	3	$ —	$ —	$ —	$ —	$ —	54,151	$ 54	$ 189,929	$ (2,982)	$ (147,066)	$ 39,935
Net loss	—	—	—	—	—	—	—	—	—	—	(25,469)	(25,469)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	973	—	973
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	14	—	14
Adoption of ASC 606, *Revenue from Contracts with Customers*	—	—	—	—	—	—	—	—	—	—	(1,641)	(1,641)
Stock based compensation expense	—	—	—	—	—	—	—	—	5,374	—	—	5,374
Issuance of common stock resulting from exercise of stock options	—	—	—	—	—	—	279	—	553	—	—	553
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	—	—	—	—	113	—	369			369
Issuance of common stock resulting from exercise of warrants	—	—	—	—	—	—	176	—	246	—	—	246
Issuance of common stock resulting from offering, net of $1,005 in offering costs	—		—	—	4	—	5,493	6	30,992	—	—	30,998
Preferred stock conversion	—	—	5	—	—	—	(5,000)	(5)	5	—	—	—
	3	—	5	—	4	—	55,212	55	227,468	(1,995)	(174,176)	51,352

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (25,469)	$ (26,754)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	632	570
Right-of-use asset amortization	408	—
Stock-based compensation	5,374	4,943
Other non-cash transactions	(69)	75
Realized investment gains	(1,161)	(1,651)
Deferred tax benefit	—	(164)
Foreign currency re-measurement loss	(61)	22
Changes in operating assets and liabilities:		
Accounts receivable	(4,055)	12,511
Prepaid expenses and other assets	(679)	(3,939)
Deferred revenue	(28,524)	9,308
Accounts payable	1,257	764
Accrued expenses and other current liabilities	(914)	3,249
Lease liabilities	794	—
Net cash (used in) operating activities	(52,467)	(1,066)
Investing activities:		
Purchase of property and equipment	(2,462)	(1,698)
Proceeds from maturities of investments	63,325	88,358
Proceeds from sale of investments	8,292	22,047
Purchase of investments	(59,317)	(117,582)
Net cash provided by/(used in) investing activities	9,838	(8,875)
Financing activities:		
Proceeds from exercise of options	553	986
Proceeds from employee stock purchase plan	369	—
Proceeds from exercise of warrants	246	314
Issuance of Common and Preferred Stock, net of issuance costs	30,998	47,211
Net cash provided by financing activities	32,166	48,511
Effect of exchange rate change on cash and cash equivalents	(2,144)	(1,581)
Net increase in cash and cash equivalents	(12,607)	36,989
Cash and cash equivalents at beginning of year	74,867	37,878
Cash and cash equivalents at end of year	$ 62,260	$ 74,867
Supplemental cash flow disclosures:		
Accretion of Series C convertible preferred stock	$ 2,830	$ —
Cash paid for income taxes	$ —	$ 908
Net unrealized gain on investments	$ 14	$ 681
Property and equipment included in accounts payable	$ 1,235	$ 241

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 acquired 100% interest in Pieris Pharmaceuticals GmbH (formerly Pieris AG, a German company which was founded in 2001) in December 2014. Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries, hereinafter collectively Pieris, or the Company, is a clinical-stage biopharmaceutical company that discovers and develops Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Pieris' corporate headquarters is located in Boston, Massachusetts and its research facility, as of December 31, 2019, was located in Freising-Weihenstephan, Germany. The Company moved its research facility to Hallbergmoos, Germany in February 2020.

Pieris's clinical pipeline includes an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma and an immuno-oncology, or IO, bispecific targeting HER2 and 4-1BB.

The Company’s core Anticalin technology and platform was developed in Germany, and the Company has partnership arrangements with several major multi-national pharmaceutical companies.

As of December 31, 2019, the Company had cash, cash equivalents and investments of $104.2 million. The Company expects that its existing cash, cash equivalents, and investments, are sufficient to support operating expense and capital expenditure requirements for at least 12 months from the date of this filing.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries were prepared in accordance with U.S. GAAP. The consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

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, 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, deferred tax liabilities and valuation allowances; determination of the incremental borrowing rate to calculate right-of-use assets and lease liabilities; beneficial conversion features; fair value of stock options, preferred stock, and warrants; 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 the Company’s 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 weighted 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 (expense) income, net in the consolidated statements of operations. Foreign currency gains and losses on available-for-sale investment transactions are recorded to other comprehensive income on the Company's balance sheet per Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 830, *Foreign Currency Matters.*

Cash, Cash Equivalents and Investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of 90 days or less from the purchase date and for which there is an active market are considered to be cash equivalents. The Company’s investments are comprised of money market, asset backed securities, government treasuries, and corporate bonds that are classified as available-for-sale in accordance with FASB ASC 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its balance sheets.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive loss on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of other income.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment, and changes in value subsequent to period end. As of December 31, 2019, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

Concentration of Credit Risk and Off-Balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents, investments, and accounts receivable. The Company's cash, cash equivalents, and investments are held in accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. Accounts receivable primarily consist of amounts due under strategic partnership and other license agreements with major multi-national pharmaceutical companies for which the Company does not obtain collateral.

Fair Value Measurement

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, or ASC 820, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

- 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.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (*Note 4*).

An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value.

Fair Values of Financial Instruments

The fair value of cash, accounts receivable, and accounts payable approximates the carrying value of these financial instruments because of the short-term nature of any maturities. The Company determines the estimated fair values of other financial instruments, using available market information and valuation methodologies, primarily input from independent third party pricing sources.

Accounts Receivable

Accounts receivable are recorded net of allowances for doubtful accounts and represent amounts due from strategic partners. The Company monitors and evaluates collectability of receivables on an ongoing basis and considers whether an allowance for doubtful accounts is necessary. The Company determined that no such reserve is needed as of December 31, 2019 and 2018. Historically, Pieris has not had collectability issues.

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	10 - 14
Office and computer equipment	3 - 13

Impairment of Long-lived Assets

The Company 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. The Company 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. The Company believes that, as of each of the balance sheets presented, none of the Company's long-lived assets were impaired.

Revenue Recognition

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin therapeutics against a variety of targets. The terms of these agreements provide for the transfer of multiple goods or services which may include: (i) licenses, or options to obtain licenses, to Pieris's Anticalin technology and/or specific programs and (ii) research and development activities to be performed on behalf of or with a collaborative partner. Payments to Pieris under these agreements may include upfront fees (which include license and option fees), payments for research and development 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.

Effective January 1, 2019, the Company adopted ASC 606. The standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The Company elected the modified retrospective approach and applied it to contracts not completed at the date of adoption. Therefore, comparative prior periods have not been adjusted. The reported results for 2019 reflect the application of ASC 606 guidance while the reported results for 2018 were prepared under the guidance of FASB ASC Topic 605, *Revenue Recognition*, or ASC 605. Furthermore, the Company adopted the contract modification practical expedient set forth in ASC 606 and will reflect the aggregate effect of all modifications that occurred before January 1, 2019 when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price to the satisfied and unsatisfied performance obligations. See Note 3 for additional details on these arrangements.

Collaborative Arrangements

The Company considers the nature and contractual terms of an arrangement and assess whether the arrangement involves a joint operating activity pursuant to which it is an active participant and exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and exposed to the significant risks and rewards with respect to the arrangement, it accounts for these arrangements pursuant to ASC 808, *Collaborative Arrangements*, or ASC 808, and applies a systematic and rational approach to recognize revenue. The Company classifies payments received as revenue and payments made as a reduction of revenue in the period in which they are earned.

Revenue from Contracts with Customers

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied.

The Company evaluates all promised goods and services within a customer contract and determines which of such goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

Licensing arrangements are analyzed to determine whether the promised goods or services, which often include licenses, research and development services and governance committee services, are distinct or whether they must be accounted for as part of a combined performance obligation. If the license is considered not to be distinct, the license would then be combined with other promised goods or services as a combined performance obligation. If the Company is involved in a governance committee, it assesses whether its involvement constitutes a separate performance obligation. When governance committee services are determined to be separate performance obligations, the Company determines the fair value to be allocated to this promised service.

Certain contracts contain optional and additional items, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. An option that is considered a material right is accounted for as a separate performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. A contract may contain variable consideration, including potential payments for both milestone and research and development services. For certain potential milestone payments, the Company estimates the amount of variable consideration by using the most likely amount method. In making this assessment, the Company evaluates factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period the Company re-evaluates the probability of achievement of such variable consideration and any related constraints. Pieris will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. For potential research and development service payments, the Company estimates the amount of variable consideration by using the expected value method, including any approved budget updates arising from additional research or development services.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price among the performance obligations on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting

amounts allocated to each performance obligation are consistent with the amount the Company would expect to receive for each performance obligation.

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price basis. 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.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non- refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

Milestones and Royalties

The Company 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, including regulatory approval. Sales milestones are 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.

There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur. For revenues from research and development milestones, payments will be recognized consistent with the recognition pattern of the performance obligation to which they relate.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Commercial milestones and sales royalties are determined by sales or usage-based thresholds and will be accounted for under the royalty recognition constraint as constrained variable consideration.

Contract Balances

The Company recognizes a contract asset when the Company transfers goods or services to a customer before the customer pays consideration or before payment is due, excluding any amounts presented as a receivable (i.e., accounts receivable). A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. The contract liabilities (i.e., deferred revenue) primarily relate to contracts where the Company has received payment but has not yet satisfied the related performance obligations.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all Company obligations under the agreement have been fulfilled.

Costs to Obtain and Fulfill a Contract with a Customer

Certain costs to obtain customer contracts, including success-based fees paid to third-party service providers, and costs to fulfill customer contracts are capitalized in accordance with FASB ASC 340, *Other Assets and Deferred Costs*, or ASC 340. These costs are amortized to expense on a systemic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates. The Company will expense the amortization of costs to obtain customer contracts to general and administrative expense and costs to fulfill customer contracts to research and development expense.

Impact of Adopting ASC 606 on the Financial Statements

As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to the consolidated balance sheet as of January 1, 2019:

	As Reported, December 31, 2018	ASC 606 Adjustment	Adjusted, January 1, 2019
Consolidated Balance Sheet Data (in thousands):			
Prepaid expenses and other current assets	$ 4,574	$ 716	$ 5,290
Other non-current assets	910	1,120	2,030
Total Assets	$ 141,341	$ 1,836	$ 143,177
Deferred revenue, net of current portion	53,303	3,477	56,780
Total Liabilities	101,406	3,477	104,883
Accumulated deficit	(147,066)	(1,641)	(148,707)
Total stockholders' equity	39,935	(1,641)	38,294
Total liabilities and stockholders' equity	$ 141,341	$ 1,836	$ 143,177

These changes were primarily caused by the differences in determining and allocating transaction price under ASC 606 and costs to obtain certain contracts under ASC 340.

The adoption of ASC 606 did not impact income taxes, as the Company fully reserves its net deferred tax assets. Therefore, the change to the Company's net deferred tax asset position due to adoption was offset by a corresponding change to the valuation allowance.

The following table compares the reported consolidated balance sheet and statement of operations, as of December 31, 2019 and for the twelve months ended December 31, 2019, to the pro-forma amounts had the previous guidance been in effect:

	December 31, 2019		
	As Reported, ASC 606	Adjustments	Adjusted Balance, ASC 605
Consolidated Balance Sheet Data (in thousands):			
Prepaids and other current assets	$ 4,072	$ (124)	$ 3,948
Other non-current assets	3,146	(815)	2,331
Total Assets	$ 141,097	$ (939)	$ 140,158
Deferred revenues, current portion	11,256	3,382	14,638
Deferred revenue, net of current portion	47,258	(9,069)	38,189
Total Liabilities	89,745	(5,687)	84,058
Accumulated Deficit	(174,176)	4,748	(169,428)
Total stockholders' equity	51,352	4,748	56,100
Total liabilities and stockholders' equity	$ 141,097	$ (939)	$ 140,158

	December 31, 2019		
	As Reported, ASC 606	Adjustments	Adjusted Balance, ASC 605
Consolidated Statement of Operations Data (in thousands):			
Revenue	$ 46,279	$ 2,315	$ 48,594
General and administrative expenses	18,440	(858)	17,582
Loss from operations	(27,157)	1,457	(25,700)
Loss before income taxes	(25,469)	1,457	(24,012)
Net loss	$ (25,469)	$ 1,457	$ (24,012)
Comprehensive loss	$ (24,482)	$ 1,457	$ (23,025)

These changes were primarily caused by the revenue recognition and related cost amortization patterns due to differences in the determination and allocation of transaction price under ASC 606 and costs to obtain certain contracts under ASC 340. The application of ASC 606 did not have an impact on the Company's net cash used in operating activities for the twelve months ended December 31, 2019 but did result in offsetting adjustments to net loss, change in other current and non-current assets, and the change in deferred revenue presented within the consolidated statements of cash flows for that period.

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 Topic 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.

The Tax Cuts and Jobs Act (TCJA) subjects a U.S. shareholder to tax on global-intangible low tax income (GILTI) earned by certain foreign subsidiaries. The Company has made an accounting policy election to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only.

Stock-based Compensation

The Company measures share-based payments in accordance with ASC Topic 718, *Stock Compensation*. Pieris records its stock-based compensation expense over the requisite service period and records forfeitures as they occur. 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. Due to the limited operating history of the Company as a public entity and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When

selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical
share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Due to the lack of Company specific historical option activity, the Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term for non-employee awards is the remaining contractual term of the option. The risk-free interest rates are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid, and does not expect to pay dividends in the foreseeable future.

All excess tax benefits and tax deficiencies are recorded as income tax expense or benefit in the Company's statement of operations and comprehensive loss. For the years ended December 31, 2019 and 2018, the Company did not record an income statement benefit for excess tax benefits as a valuation allowance is also required on these amounts.

Leases

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842)*, or ASC 842. Under the amendments in ASC 842, 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. The Company adopted ASC 842 in the fourth quarter of 2019 using the required modified retrospective approach, effective January 1, 2019. As a result, prior periods are presented in accordance with the previous guidance in ASC 840, Leases, or ASC 840.

The Company elected the package of practical expedients permitted under the transition guidance within the new standard expedients which allows the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of its existing leases as of the transition date, and the treatment of initial direct costs. In addition, the Company elected the practical expedient not to apply the recognition requirements in the lease standard to short-term leases (a lease that at commencement date has a lease term of 12 months or less and does not contain a purchase option that it is reasonably certain to exercise) and the practical expedient to not separate lease and non-lease components for all asset classes. Any variable components of lease costs are excluded from lease payments and are recognized in the period incurred.

The Company determines if an arrangement is a lease at inception. The Company's contracts are determined to contain a lease within the scope of ASC 842 when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company's lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term and based on observable market data points. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis.

The Company typically only includes an initial lease term in its assessment of a lease agreement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The expected lease term includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right

of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

The adoption of the new standard resulted in recording a transition adjustment on January 1, 2019 of right-of-use assets of $0.9 million and lease liabilities of $0.9 million for operating leases and the derecognition of deferred rent originally accounted for under legacy guidance. The adoption did not have a material impact on the consolidated statement of operations. See Note 12 for additional details.

Impact of Adopting ASC 842 on the Financial Statements

	As Reported, December 31, 2018	ASC 842 Adjustment	Adjusted, January 1, 2019
Consolidated Balance Sheet Data (in thousands):			
Operating lease right-of-use assets (1)	—	868	868
Deferred rent (2)	35	(35)	—
Current operating lease liabilities (3)	—	442	442
Non-current operating lease liabilities (3)	—	461	461

(1) Represents capitalization of operating lease right-of-use assets.

(2) Represents reclassification of deferred rent to operating lease right-of-use assets.

(3) Represents recognition of operating lease liabilities.

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. The Company 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, the Company determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, the Company 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. The Company operates as a single segment dedicated to the discovery and development of biotechnological applications and the Company’s chief operating decision maker, or CODM, makes decisions based on the Company as a whole. The Company has determined that its CODM is its Chief Executive Officer.

Earnings per Share

Basic earnings per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents.

Diluted earnings per share attributable to common stockholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share attributable to common stockholders' calculation, preferred stock, stock options, unvested restricted stock, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Recent Accounting Pronouncements Not Yet Adopted

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808):Clarifying the Interaction between Topic 808 and Topic 606*, or ASU 2018-18. ASU 2018-18 makes targeted improvements to generally accepted

accounting principles for collaborative arrangements, including: clarification that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adding unit-of-account guidance in Topic 808 to align with the guidance in ASC 606; and a requirement that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. The Company is currently evaluating the impact of adoption, but this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*, or ASU 2016-13. ASU 2016-13 significantly changes the impairment model for most financial assets and certain other instruments. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value, and requires the reversal of previously recognized credit losses if fair value increases. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset.

Subsequently, in November 2018 the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326*, *Financial Instruments-Credit Losses*, or ASU 2018-19, which clarifies codification and corrects unintended application of the guidance. In November 2019, the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326*, *Financial Instruments-Credit Losses*, or ASU 2019-11 which clarifies or addresses specific issues about certain aspects of ASU 2016-13. In November 2019 the FASB also issued ASU No. 2019-10, *Financial Instruments-Credit Losses (Topic 326)*, *Derivatives and Hedging (Topic 815)*, *and Leases (Topic 842): Effective Dates*, or ASU 2019-10, which delays the effective date of ASU 2016-13 by three years for certain smaller reporting companies such as the Company. The guidance in ASU 2016-13 is effective for the Company for financial statements issued for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years, with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

The Company 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 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 from contracts with customers (option, license and collaboration agreements), which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments.

During the years ended December 31, 2019 and 2018, respectively, the Company recognized revenues as follows (in thousands):

	Years Ended December 31,	
	2019	2018
Revenue from contract with customers	$ 43,646	$ 27,248
Collaboration revenue	2,633	1,762
Other revenues	—	91
Total Revenue	$ 46,279	$ 29,101

During the years ended December 31, 2019 and 2018, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Years Ended December 31,	
	2019	2018
AstraZeneca	$ 25,828	$ 17,632
Seattle Genetics	2,493	5,413
Servier	15,048	4,508
Other	2,910	1,548
Total Revenue	$ 46,279	$ 29,101

Under the Company´s existing strategic partnerships and other license agreements, the Company could receive the following potential milestone payments (in millions):

	Research, Development, Regulatory & Commercial Milestones	Sales Milestones
AstraZeneca	$ 1,111	$ 960
Servier	799	707
Seattle Genetics	769	450
Total potential milestone payments	$ 2,679	$ 2,117

Strategic Partnerships

Seattle Genetics

On February 8, 2018, the Company entered into a license and collaboration agreement, or the Seattle Genetics Collaboration Agreement, and a non-exclusive Anticalin platform technology license agreement, or the Seattle Genetics Platform License, and together with the Seattle Genetics Collaboration Agreement, the Seattle Genetics Agreements, with Seattle Genetics, Inc., or Seattle Genetics, pursuant to which the parties will develop multiple targeted bispecific IO treatments for solid tumors and blood cancers.

Under the terms of the Seattle Genetics Agreements, the companies will pursue multiple antibody-Anticalin fusion proteins during the research phase. The Seattle Genetics Agreements provide Seattle Genetics a base option to select up to three programs for further development. Prior to the initiation of a pivotal trial, the Company may opt into global co-development and U.S. commercialization of the second program and share in global costs and profits on an equal basis. Seattle Genetics will solely develop, fund and commercialize the other two programs. Seattle Genetics may also decide to select additional candidates from the initial research phase for further development in return for the payment to us of additional fees, milestone payments, and royalties

The Seattle Genetics Platform License grants Seattle Genetics a non-exclusive license to certain intellectual property related to the Anticalin platform technology.

Upon signing the Seattle Genetics Agreements, Seattle Genetics paid the Company a $30.0 million upfront fee and an additional $4.9 million was estimated to be paid for research and development services as reimbursement to the Company through the end of the research term. In addition, the Company may receive tiered royalties on net sales up to the low double-digits and up to $1.2 billion in total success-based research, development, commercial, and sales milestones payments across the product candidates, depending on the successful development and commercialization of those candidates. If Seattle Genetics exercises its option to select additional candidates from the initial research phase for further development, payment to Pieris of additional fees, milestone payments, and royalties would result.

The term of each of the Seattle Genetics Agreements ends upon the expiration of all of Seattle Genetics' payment obligations under each agreement. The Seattle Genetics Collaboration Agreement may be terminated by Seattle Genetics on a product-by-product basis for convenience beginning 12 months after its effective date upon 90 days' notice or, for any program where a pivotal study has been initiated, upon 180 days' notice. Any program may be terminated at Seattle Genetics' option. If any program is terminated by Seattle Genetics after a pre-defined pre-clinical stage, the Company will have full rights to continue such program. If any program is terminated by Seattle Genetics prior to such pre-defined pre-clinical stage, the Company will have the right to continue to develop such program, but will be obligated to offer a co-development option to Seattle Genetics for such program. The Seattle Genetics Collaboration Agreement may also be terminated by Seattle Genetics or the Company for an uncured material breach by the other party upon 90 days' notice, subject to extension for an additional 90 days if the material breach relates to diligence obligations and subject, in all cases, to dispute resolution procedures. The Seattle Genetics Collaboration Agreement may also be terminated due to the other party's insolvency and may in certain instances, including for reasons of safety, be terminated on a product-by-product basis. Each party may also terminate the Seattle Genetics Agreements if the other party challenges the validity of any patents licensed under the Seattle Genetics Agreements, subject to certain exceptions. The Seattle Genetics Platform License will terminate upon termination of the Seattle Genetics Collaboration Agreement, whether in its entirety or on a product-by-product basis.

The Company determined that the Seattle Genetics Agreements should be combined and evaluated as a single arrangement under ASC 606 as they were executed on the same date. The arrangement with Seattle Genetics provides for the transfer of the following

goods or services: (i) three candidate research licenses that each consist of a non-exclusive platform technology license, a co-exclusive candidate research license, and research and development services, (ii) research, development and manufacturing services associated with each candidate research license, (iii) participation on various governance committees, and (iv) two antibody target swap options which were assessed as material rights.

Management evaluated all of the promised goods or services within the contract and determined which such goods and services were separate performance obligations. The Company determined that the licenses granted, at arrangement inception, should be combined with the research and development services to be provided for the related antibody target programs as they are not capable of being distinct. A third party would not be able to provide the research and development services due to the specific nature of the intellectual property and knowledge required to perform the services, and Seattle Genetics could not benefit from the licenses without the corresponding services. The Company determined that the participation on the various governance committees was distinct as the services could be performed by an outside party.

As a result, management concluded there are six separate performance obligations at the inception of the Seattle Genetics Agreements: (i) three combined performance obligations, each comprised of a non-exclusive platform technology license, a co-exclusive candidate research license, and research and development services for the first three approved Seattle Genetics antibody target programs, (ii) two performance obligations each comprised of a material right for an antibody target swap option for the first and the second approved Seattle Genetics antibody target for no additional consideration, and (iii) one performance obligation comprised of the participation on the various governance committees.

The Company allocated consideration to the performance obligations based on the relative proportion of their standalone selling prices. The Company developed standalone selling prices for licenses by applying a risk adjusted, net present value, estimate of future potential cash flows approach, which included the cost of obtaining research and development services at arm's length from a third-party provider, as well as internal full-time equivalent costs to support these services. The Company developed the standalone selling price for committee participation by using management's estimate of the anticipated participation hours multiplied by a market rate for comparable participants.

The transaction price at inception is comprised of fixed consideration of $30.0 million in upfront fees and variable consideration of $4.9 million of estimated research and development services to be reimbursed as research and development occurs through the research term. The $30.0 million upfront fee, which represents the fixed consideration in the transaction price, was allocated to each of the performance obligations based on the relative proportion of their standalone selling prices. The $4.9 million in variable consideration related to the research and development services is allocated specifically to the three target program performance obligations based upon the budgeted services for each program

The amounts allocated to the performance obligations for the three research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term of the individual research programs. The amounts allocated to the material right for the antibody target swap option will be recognized either at the time the material right expires, or if exercised, on a proportional performance basis over the estimated research term for that program. The amounts allocated to the participation on each of the committees will be recognized straight-line over the anticipated research term for all research programs. As of December 31, 2019, there was $24.7 million of aggregate transaction price allocated to remaining performance obligations.

Under the Seattle Genetics Agreements, the Company is eligible to receive various research, development, commercial and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur.
As of December 31, 2019, there is $4.5 million and $16.0 million of current and non-current deferred revenue, respectively, related to the Seattle Genetics Agreements.

AstraZeneca
On May 2, 2017, the Company entered into a license and collaboration agreement, or the AstraZeneca Collaboration Agreement, and a non-exclusive Anticalin platform technology license agreement, or AstraZeneca Platform License, and together with the AstraZeneca Collaboration Agreement, the AstraZeneca Agreements with AstraZeneca AB, or AstraZeneca, which became effective on June 10, 2017, following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Under the AstraZeneca Agreements the parties will advance several novel inhaled Anticalin proteins.

In addition to the Company's lead inhaled drug candidate, PRS-060/AZD1402, or the AstraZeneca Lead Product, the Company and AstraZeneca will also collaborate to progress four additional novel Anticalin proteins against undisclosed targets for respiratory diseases, or the AstraZeneca Collaboration Products, and together with the AstraZeneca Lead Product, the AstraZeneca Products.

The Company is responsible for advancing the AstraZeneca Lead Product through its phase 1 study, with the associated costs funded by AstraZeneca. The parties will collaborate thereafter to conduct a phase 2a study in asthma patients, with AstraZeneca continuing to fund development costs. After completion of a phase 2a study, Pieris has the option to co-develop the AstraZeneca Lead Product and also has a separate option to co-commercialize the AstraZeneca Lead Product in the United States. For the AstraZeneca Collaboration Products, the Company will be responsible for the initial discovery of the novel Anticalin proteins, after which AstraZeneca will take the lead on continued development of the AstraZeneca Collaboration Products. The Company has the option to co-develop two of the four AstraZeneca Collaboration Products beginning at a pre-defined preclinical stage and would also have the option to co-commercialize these two programs in the United States, while AstraZeneca will be responsible for development and commercialization of the other programs worldwide.

The term of each of the AstraZeneca Agreements ends upon the expiration of all of AstraZeneca's payment obligations under such agreement. The AstraZeneca Collaboration Agreement may be terminated by AstraZeneca in its entirety for convenience beginning 12 months after its effective date upon 90 days' notice or, if the Company has obtained marketing approval for the marketing and sale of a product, upon 180 days' notice. Each program may be terminated at AstraZeneca's option; if any program is terminated by AstraZeneca, the Company will have full rights to such program. The AstraZeneca Collaboration Agreement may also be terminated by AstraZeneca or the Company for material breach upon 180 days' notice of a material breach (or 30 days with respect to payment breach), provided that the applicable party has not cured such breach by the permitted cure period (including an additional 180 days if the breach is not susceptible to cure during the initial 180-day period) and dispute resolution procedures specified in the agreement have been followed. The AstraZeneca Collaboration Agreement may also be terminated due to the other party's insolvency and may in certain instances be terminated on a product-by-product and/or country-by-country basis. Each party may also terminate an AstraZeneca Agreement if the other party challenges the validity of patents related to certain intellectual property licensed under such AstraZeneca Agreement, subject to certain exceptions for infringement suits, acquisitions and newly-acquired licenses. The AstraZeneca Platform License will terminate upon termination of the AstraZeneca Collaboration Agreement, on a product-by-product and/or country-by-country basis.

At inception, AstraZeneca is granted the following licenses: (i) research and development license for the AstraZeneca Lead Product, (ii) commercial license for the AstraZeneca Lead Product, (iii) individual research licenses for each of the four AstraZeneca Collaboration Products, (iv) individual commercial licenses for each of the four AstraZeneca Collaboration Products, and (v) individual non-exclusive platform technology licenses for the AstraZeneca Lead Product and the four AstraZeneca Collaboration Products. AstraZeneca will be granted individual development licenses for each of the four AstraZeneca Collaboration Products upon completion of the initial discovery of Anticalin proteins.

The collaboration will be managed on an overall basis by a Joint Steering Committee, or JSC, formed by an equal number of representatives from the Company and AstraZeneca. In addition to the JSC, the AstraZeneca Collaboration Agreement also requires each party to designate an alliance manager to facilitate communication and coordination of the parties' activities under the agreement, and further requires participation of both parties on a joint development committee, or JDC, and a commercialization committee. The responsibilities of these committees vary, depending on the stage of development and commercialization of each product.

Under the AstraZeneca Agreements, the Company received an upfront, non-refundable payment of $45.0 million. In addition, the Company will receive payments to conduct a phase 1 clinical study for the AstraZeneca Lead Product. The Company is also eligible to receive research, development, commercial, sales milestone payments, and royalty payments. The Company may receive tiered royalties on sales of potential products commercialized by AstraZeneca and for co-developed products, gross margin share on worldwide sales equal dependent on the Company's level of committed investment.

Prior to the adoption of ASC 606, the budgeted research and development services for the AstraZeneca Lead Product increased and were approved by the JSC. The increases included additional phase 1 services as well as the addition of certain phase 2a services. The Company determined that these increases were contract modifications. Upon the adoption of ASC 606, the Company reflected the aggregate effects of these modifications as of the last modification date.

The Company determined that the AstraZeneca Agreements should be combined and evaluated as a single arrangement under ASC 606 as they were executed on the same date. The arrangement with AstraZeneca, including the impact of any modifications, provides for the transfer of the following goods and services: (i) five non-exclusive platform technology licenses, (ii) research and development license for the AstraZeneca Lead Product, (iii) commercial license for the AstraZeneca Lead Product, (iv) development and manufacturing services for the AstraZeneca Lead Product (or the phase 1 services), (v) technology transfer services for the AstraZeneca Lead Product, (vi) research services related to the AstraZeneca Lead Product, (vii) participation on each of the committees, (viii) four research licenses for the AstraZeneca Collaboration Products, (ix) four commercial licenses for the AstraZeneca Collaboration Products, (x) research services for the AstraZeneca Collaboration Products and (xi) certain

phase 2a services for the AstraZeneca Lead Product. Additionally, as the development licenses on the four AstraZeneca Collaboration Products may be granted at a discount in the future, the Company determined such discounts should be assessed as material rights at inception.

Management evaluated all of the promised goods or services within the contract and determined which such goods and services
were separate performance obligations. The Company determined that the licenses granted for the AstraZeneca Lead Product at the inception of the arrangement should be combined with the research services related to the AstraZeneca Lead Product and the licenses granted for the AstraZeneca Collaboration Products should be combined with the research services for the AstraZeneca Collaboration Products, as the licenses are not capable of being distinct. A third party would not be able to provide the research and development services, due to the specific nature of the intellectual property and knowledge required to perform the services and AstraZeneca could not benefit from the licenses without the corresponding services. The Company also determined that each of the phase 1 services and the phase 2a services for the AstraZeneca Lead Product were distinct and that the participation on the various committees was also distinct as all of the phase 1 services, phase 2a services and the committee services could be performed by an outside party. The Company determined that the commercial licenses for the AstraZeneca Collaboration Products granted at the inception of the arrangement should be combined with the development licenses for the AstraZeneca Collaboration Products as the company would not benefit from the commercial license without the ability to develop each product.

As a result, management concluded that there were 16 performance obligations: (i) combined performance obligation comprised of a non-exclusive platform technology license, research and development license, and commercial licenses for the AstraZeneca Lead Product and research services for the AstraZeneca Lead Product, (ii) combined performance obligation comprised of development and manufacturing services, and technology transfer services for the AstraZeneca Lead Product, (iii) committee participation, (iv-vii) four combined performance obligations each comprised of a non-exclusive platform technology license, research licenses, and research services for each AstraZeneca Collaboration Product (viii-xi) four performance obligations comprised of a material right to acquire the development licenses granted for the AstraZeneca Collaboration Products, (xii-xv) four performance obligations comprised of the commercial licenses granted for the AstraZeneca Collaboration Products and (xvi) phase 2a services.

The Company allocated consideration to the performance obligations based on the relative proportion of their standalone selling prices. The Company developed standalone selling prices for licenses and corresponding research services by applying a risk adjusted, net present value, estimate of future potential cash flow approach, which included the cost of obtaining research services at arm's length from a third-party provider, as well as internal full-time equivalent costs to support these services. The Company developed its standalone selling price for development and manufacturing services, and technology transfer services for the AstraZeneca Lead Product using estimated internal and external costs to be incurred.

The Company developed its standalone selling price for committee participation by using management's estimate of the anticipated participation hours multiplied by a market rate for comparable participants.

The Company developed its standalone selling price for the commercial licenses and material rights granted on the development licenses by probability weighting multiple cash flow scenarios using the income approach.

The transaction price was comprised of fixed consideration of $45.0 million in upfront fees and variable consideration of (i) $14.2 million in estimated phase 1 services, (ii) $12.5 million in milestone payments achieved upon the initiation of a phase 1 study in December 2017, and (iii) $4.7 million in estimated phase 2a services. The $45.0 million upfront fee, which represents the fixed consideration in the transaction price, was allocated to each of the performance obligations based on the relative proportion of their standalone selling prices. Variable consideration of $14.2 million is related to the phase 1 services and will be allocated entirely to the performance obligation to which they relate. Variable consideration of $12.5 million related to the phase 1 trial milestone was allocated by relative selling price to the combined performance obligation comprised of a non-exclusive platform technology license, research and development license and commercial licenses for the AstraZeneca Lead Product and research services for the AstraZeneca Lead Product, and the combined performance obligation comprised of development and manufacturing services and technology transfer services for the AstraZeneca Lead Product performance obligations. Variable consideration of $4.7 million for phase 2a services was allocated specifically to the related performance obligation.

The amounts allocated to the license performance obligation for the AstraZeneca Lead Product and the four performance obligations for the four research licenses for AstraZeneca Collaboration Products will be recognized on a proportional performance basis as the activities are conducted over the life of the arrangement. The amounts allocated to the performance obligation for phase 1 services, technology transfer services for the AstraZeneca Lead Product will be recognized on a proportional performance basis over the estimated term of development through phase 2a study. The amounts allocated to the performance obligation for phase 2a services for the AstraZeneca Lead Product will be recognized on a proportionate performance basis over an estimated term of 12 months. The amounts allocated to the performance obligation for participation on each of the committees will be recognized

on a straight-line basis over the expected term of development of the AstraZeneca Lead Product and the AstraZeneca Collaboration Products. The term of performance is approximately five years. The amounts allocated to the four performance obligations for the material rights to acquire a development license and the four performance obligations for commercial licenses for the AstraZeneca Collaboration Products will be recognized upon exercise of the specific material right and delivery of each of the development licenses. As of December 31, 2019, there was $26.0 million of aggregate transaction price allocated to remaining performance obligations.

Additionally, the Company evaluated payments required to be made between both parties as a result of the shared development costs of the AstraZeneca Lead Product and the two AstraZeneca Collaboration Products for which the Company has a co-development option. The Company will classify payments made as a reduction of revenue and will classify payments received as revenue, in the period they are earned.

Under the AstraZeneca Agreements, the Company is eligible to receive various research, development, commercial and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones, other than the phase 1 initiation milestone achieved in December 2017 and included in the impact of adoption of ASC 606, will be constrained until it is deemed probable that a significant revenue reversal will not occur.

In October 2019, the JSC formally approved the termination of a certain performance obligation determined at the origination of the agreement, resulting in the acceleration of remaining revenue associated with the performance obligations. The JSC's termination of the performance obligations does not impact the remainder of the Pieris-AstraZeneca alliance and the parties continue to advance the Lead Product through Phase 2a activities.

As of December 31, 2019, there is $1.0 million and $17.5 million of current and non-current deferred revenue, respectively, related to the AstraZeneca Agreements.

The Company incurred $1.6 million of third-party success fees to obtain the contract with AstraZeneca. Upon adoption of ASC 606, the Company capitalized $1.1 million in accordance with ASC 340. As of December 31, 2019, the remaining balance of the asset recognized from transaction costs to obtain the AstraZeneca contract is $0.7 million. Amortization during the year ended December 31, 2019, was $0.4 million.

Servier

On January 4, 2017, the Company entered into a license and collaboration agreement, or Servier Collaboration Agreement, and a non-exclusive Anticalin platform license agreement, or Servier Platform License, and together with the Servier Collaboration Agreement, the Servier Agreements with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, pursuant to which the Company and Servier agreed to initially pursue five bispecific therapeutic programs.

Five committed programs were initially defined, which may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on the Company's proprietary platform to generate innovative IO bispecific drug candidates, or the Collaboration Products. The collaboration may be expanded by up to three additional therapeutic programs. The Company had the option to co-develop and retain commercial rights in the United States for PRS-332, the initial lead program under the collaboration, or the Initial Lead, and has a similar option on up to three additional programs, or the Co-Development Collaboration Products, while Servier will be responsible for development and commercialization of the other programs worldwide, or the Servier Worldwide Collaboration Products. Each party is responsible for an agreed upon percentage of shared costs, as set forth in the budget for the collaboration plan, and as further discussed below.

The Co-Development Collaboration Products may be jointly developed, according to a collaboration plan, through marketing approval from the U.S. Food and Drug Administration or the European Medicines Agency. Servier Worldwide Collaboration Products may be jointly developed, according to a collaboration plan, through specified preclinical activities, at which point Servier becomes responsible for further development of the Collaboration Product.

At inception, Servier was granted the following licenses: (i) development license for the Initial Lead, (ii) commercial license for the Initial Lead, (iii) individual research licenses for each of the four Collaboration Products, and (iv) individual non-exclusive platform technology licenses for the Initial Lead and for each of the four Collaboration Products. Upon achievement of certain development activities, specified by the collaboration for each Servier Agreement, Servier will be granted a development license and a commercial license. For the Initial Lead and the Co-Development Collaboration Products, the licenses granted are with respect to the entire world except for the United States. For Servier Worldwide Collaboration Products, the licenses granted are with respect to the entire world.

The Servier Agreements are managed on an overall basis by a joint executive committee, or JEC, formed by an equal number of members from the Company and Servier. Decisions by the JEC will be made by consensus; however, in the event of a disagreement, each party will have final-decision making authority as it relates to the applicable territory in which such party has commercialization rights for the applicable product. In addition to the JEC, the Servier Collaboration Agreement requires the participation of both parties on: (i) a JSC, (ii) a JDC, (iii) a joint intellectual property committee, or JIPC, and (iv) a joint research committee, or JRC. The responsibilities of these committees vary, depending on the stage of development and commercialization of the Collaboration Products.

For the Initial Lead and Co-Development Collaboration Products, the Company and Servier are responsible for an agreed upon percent of the shared costs required to develop the products through commercialization. In the event that the Company fails to exercise its option to co-develop the Co-Development Collaboration Products, Servier has the right to continue with the development and will be responsible for all costs required to develop the products through commercialization.

Under the Servier Agreements, the Company received an upfront, non-refundable payment of €30.0 million (approximately $32.0 million). In addition, the Company is eligible to receive research, development, commercial, and sales milestone payments as well as tiered royalties up to low double digits on the sales of commercialized products in the Servier territories. The Company achieved two preclinical milestones under the program, one in December 2018 for €0.5 million (approximately $0.6 million) and another in February 2019 for €1.5 million (approximately $1.7 million), both of which became billable on their respective achievement dates.

The initial research collaboration term, as it relates to the Initial Lead and Collaboration Products, shall continue for three years from the effective date of the Servier agreements, and may be mutually extended for two one-year terms consecutively applied.
The term of each Servier Agreement ends upon the expiration of all of Servier's payment obligations under such Servier Agreement. The Servier Agreements may be terminated by Servier for convenience beginning 12 months after their effective date upon 180 days' notice. The Servier Agreements may also be terminated by Servier or the Company for material breach upon 90 days' or 120 days' notice under the Servier Collaboration Agreement and the Servier Platform License, 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 Servier Agreement have been followed. The Servier 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 Servier Platform License will terminate upon termination of the Servier Collaboration Agreement, on a product-by-product and/or country-by-country basis. In February 2020, the research term was extended for another 12 months.

As the Company and Servier are considered to be active participants in the Servier Agreements and are exposed to significant risks and rewards, certain units of account within the Servier Agreements are within the scope of ASC 808. The arrangement with Servier provides for the transfer of the following goods and services: (i) five non-exclusive platform technology licenses, a development license, a commercial license and research and development services for the Initial Lead, (ii) participation on each of the committees, (iii) four research licenses for Collaboration Products, and (iv) research and development services for the Collaboration Products. Additionally, as the development and commercial licenses on the four Collaboration Products may be granted at a discount in the future, the Company determined such discounts should be assessed as material rights at inception.

Management evaluated all of the promised goods or services within the contract and determined which goods and services
were separate performance obligations. The Company determined that the licenses granted at the inception of the Servier collaboration, should be combined with the research and development services to be provided for the Initial Lead and Collaboration Products, over the term of the Servier Agreements, as such licenses are not capable of being distinct. A third party would not be able to provide the research and development services, due to the specific nature of the intellectual property and knowledge required to perform the services, and Servier could not benefit from the licenses without the corresponding services. The Company determined that the participation on the various committees was distinct as the services could be performed by an outside party.
As a result, management concluded that there are 10 performance obligations at the inception of the Servier Agreements. The following performance obligations are within the scope of ASC 808: (i) combined performance obligation comprised of a non-exclusive platform technology license, commercial license, development license and research and development services for the Initial Lead, (ii) two separate performance obligations each comprised of a combined non-exclusive platform technology license, research license, and research and development services for each Co-Development Collaboration Product (iii) one performance obligation comprised of participation in the various governance committees, and (iv) two combined performance obligations comprised of the development and commercial licenses granted for the Co-Development Collaboration Products (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in material rights. The following performance obligations are within the scope of ASC 606: (i) two separate performance obligations each comprised of a combined non-exclusive platform technology license, research license and research and development services for each Servier Worldwide

Collaboration Product, and (ii) two combined performance obligations comprised of the development and commercial licenses granted for the Servier Worldwide Collaboration Products (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in material rights.

The Company allocated consideration to the performance obligations based on the relative proportion of their standalone selling prices. The Company developed its standalone selling prices for licenses by applying a risk adjusted, net present value, estimate of future potential cash flows approach, which included the cost of obtaining research and development services at arm's length from a third-party provider, as well as internal full-time equivalent costs to support these services.

The Company developed its estimate of standalone selling price for committee participation by using management's estimate of the anticipated participation hours multiplied by a market rate for comparable participants.

The Company developed its estimate of standalone selling price for the material rights granted on the development and commercial licenses granted for the Collaboration Products by probability weighting multiple cash flow scenarios using the income approach.

The transaction price at inception is comprised of the fixed upfront fee of €30.0 million (approximately $32.0 million) and was allocated to the performance obligations based on the relative proportion of their standalone selling prices.

The amounts allocated to the performance obligation for the Initial Lead and the four performance obligations for the four research and development licenses for Collaboration Products will be recognized on a proportional performance basis as the activities are conducted over the life of the arrangement. The term of the performance at inception of the Servier Agreements for the Initial Lead and each of the Co-Development Collaboration Products may be through approval of certain regulatory bodies; a period which could be many years. The term of the performance for each of the other two Servier Worldwide Collaboration Products is through the initial research and collaboration term, plus potential extensions. The amounts allocated to the performance obligation for participation on each of the committees will be recognized on a straight-line basis over the anticipated performance period over the entirety of the arrangement with Servier. The amounts allocated to the four performance obligations for the material rights to acquire development and commercial licenses for the Co-Development Collaboration Products are granted in the future will be recognized over time upon delivery of each of the licenses through marketing approval. The amounts allocated to the four performance obligations for the material rights to acquire development and commercial licenses for the Servier Developed Collaboration Products are granted in the future will be recognized upon delivery of each of the licenses. As of December 31, 2019, there was $19.4 million of aggregate transaction price allocated to remaining performance obligations.

Additionally, the Company evaluated payments required to be made between both parties as a result of the shared development costs of the Initial Lead and Collaboration Products. The Company will classify payments made as a reduction of revenue and will classify payments received as revenue, in the period they are earned.

Under the Servier Agreements the Company is eligible to receive various research, development, commercial, and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur.

In September 2019, Servier notified the Company of its decision to discontinue co-development of PRS-332, a PD-1-LAG-3 bispecific that served as the initial development program under the Pieris-Servier alliance, for strategic reasons. The Company does not presently intend to continue development of PRS-332 but retains full rights to advance the development and commercialization of the product on a world-wide basis in the future. Servier's termination of the co-development of the PRS-332 program does not impact the remainder of the Pieris-Servier alliance and the parties continue to advance PRS-344 through IND-enabling activities. The Pieris-Servier alliance includes three additional programs beyond PRS-344, all of which are in active preclinical development.

In addition, effective in January 2020, Servier and the Company agreed to extend the research collaboration term for one year. This extension includes reimbursement for the Company's internal efforts and an extension of the research license.

As of December 31, 2019, there is $5.7 million and $13.7 million of current and non-current deferred revenue, respectively, related to the Servier Agreements.

The Company incurred costs to obtain the contract with Servier. Upon adoption of ASC 606, the Company capitalized $0.5 million of third-party service fees in accordance with ASC 340. As of December 31, 2019, the remaining balance of the asset recognized from costs to obtain the Servier contract is $0.3 million. Amortization during the twelve months ended December 31, 2019 was $0.2 million.

Other License Agreements

ASKA

On February 27, 2017 the Company entered into an exclusive option agreement, or the ASKA Option Agreement with ASKA Pharmaceutical Co., Ltd., or ASKA, pursuant to which Pieris granted ASKA an option to acquire (i) a non-exclusive license to certain intellectual property rights associated with the Company's Anticalin platform, and (ii) an exclusive license to certain intellectual property rights specifically related to the Company's PRS-080 Anticalin protein, in order to develop, manufacture, import, sale, export, and offer for sale and export any pharmaceutical formulation containing PRS-080, the Company's PEGylated Anticalin protein targeting hepcidin, or the Licensed Product, in Japan and certain other Asian territories.

Upon receipt, ASKA had up to 60 days to evaluate the results of the phase 2a study, or the Evaluation Period. In November 2019, the Company delivered the finals results of the study to ASKA, thus triggering the 60-day evaluation period.

The Company determined that the completed phase 2a study represents the sole good or service to be transferred, and the only performance obligation under the ASKA Option Agreement for which an upfront payment of $2.75 million was received from ASKA. With the formal delivery of the final results in November 2019, the full $2.75 million revenue that was previously constrained was recognized in connection with this arrangement for the year ended December 31, 2019. No revenue under this arrangement was recognized 2018.

On January 20, 2020 ASKA notified us that it does not intend to exercise its option to obtain an exclusive license to develop and commercialize the PRS-080. The term of the ASKA Option Agreement ended as of the date of ASKA's notification of its decision not to exercise its option rights.

In connection with obtaining the contract with ASKA, the Company additionally incurred $0.3 million in third-party service fees which were capitalized in accordance with ASC 340. Amortization during the twelve months ended December 31, 2019 was $0.3 million and thus, as of December 31, 2019, there was no remaining balance of the asset recognized from costs to obtain the ASKA contract.

Contract Balances

The Company receives payments from its collaboration partners based on payments established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under each arrangement. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right is unconditional.

There were no additions to deferred revenue during the twelve months ended December 31, 2019 and reductions to deferred revenue were $32.2 million for the twelve months ended December 31, 2019.

4. Cash, Cash Equivalents and Investments

As of December 31, 2019 and 2018, cash, cash equivalents and investment comprised funds in depository, money market accounts, U.S. treasury securities, asset backed securities, and corporate bonds. The following table presents the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 at December 31, 2019 and 2018 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2019				
Money market funds, included in cash equivalents	$ 47,384	$ 47,384	$ —	$ —
Investments - US treasuries	5,300	5,300	—	—
Investments - Asset-backed securities	7,950	—	7,950	—
Investments - Corporate bonds	28,644	—	28,644	—
Total	$ 89,278	$ 52,684	$ 36,594	$ —

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2018				
Money market funds, included in cash equivalents	$ 7,791	$ 7,791	$ —	$ —
Corporate bonds, included in cash equivalents	10,910	—	10,910	—
Investments - US treasuries	7,518	7,518	—	—
Investments - Asset-backed securities	5,758	—	5,758	—
Investments - Corporate bonds	39,964	—	39,964	—
Total	$ 71,941	$ 15,309	$ 56,632	$ —

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of December 31, 2019.

Investments at December 31, 2019 consist of the following (in thousands):

	Contractual maturity (in days)	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments					
US treasuries	46-182	$ 5,293	$ 25	$ (18)	$ 5,300
Asset-backed securities	49-106	7,962	12	(24)	7,950
Corporate bonds	2-204	28,709	20	(85)	28,644
Total		$ 41,964	$ 57	$ (127)	$ 41,894

Investments at December 31, 2018 consist of the following (in thousands):

	Contractual maturity (in days)	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments					
US treasuries	150-164	$ 7,541	$ —	$ (23)	$ 7,518
Asset-backed securities	196-259	5,766	1	(9)	5,758
Corporate bonds	73-252	40,072	3	(111)	39,964
Total		$ 53,379	$ 4	$ (143)	$ 53,240

There were $0.3 million and $1.0 million of realized gains for the year ended December 31, 2019 and 2018, respectively.

5. Property and Equipment, Net

Property and equipment are summarized as follows (in thousands):

	Years Ended December 31,	
	2019	2018
Laboratory equipment	$ 11,635	$ 7,431
Office and computer equipment	724	661
Leasehold improvements	10,710	323
Property and equipment at cost	23,069	8,415
Accumulated depreciation	(3,567)	(3,366)
Property and equipment, net	$ 19,502	$ 5,049

Depreciation expense was $0.6 million and $0.6 million for the years ended December 31, 2019 and 2018, respectively. There were no other changes in accumulated depreciation other than the foreign currency impact.

6. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following (in thousands):

	Years Ended December 31,	
	2019	2018
Accrued accounts payable	$ 4,251	$ 943
Compensation expense	2,870	2,380
Research and development fees	1,048	1,945
Lease liabilities	733	—
Audit and tax fees	522	378
Other current liabilities	458	945
Accrued license obligations	62	2,523
Total	$ 9,944	$ 9,114

7. Income Taxes

The Company reported a loss before income taxes consisting of the following (in thousands):

	Years Ended December 31,	
	2019	2018
Domestic	$ (12,063)	$ (10,633)
Foreign	(13,406)	(16,433)
Loss before income taxes	$ (25,469)	$ (27,066)

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

	Years Ended December 31,	
	2019	2018
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	(148)
Total current	—	(148)
Deferred:		
Federal	—	—
State	—	—
Foreign	—	(164)
Total deferred	—	(164)
(Benefit) provision for income taxes	$ —	$ (312)

The reconciliation of the federal statutory rate to the Company’s effective tax rate is as follows:

	2019	2018
Federal income tax rate	21.0 %	21.0 %
Tax Reform - Change in enacted rate	—	—
Foreign rate differential	1.9	7.4
State tax, net of federal benefit	2.6	0.7
US tax on foreign income	(1.2)	(8.1)
Share-based awards compensation	(2.5)	2.0
Permanent items	(1.0)	0.8
Other	0.8	0.5
Rate change - trade tax NOL	(6.4)	—
Change in valuation allowance	(15.2)	(23.1)
Effective income tax rate	— %	1.2 %

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 (in thousands):

	Years Ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 30,455	$ 27,879
Share-based awards compensation	2,705	2,359
Accrued expenses	328	304
Depreciation and other	53	125
Deferred revenue	—	641
Unrealized foreign currency	90	—
Lease liability	4,378	—
Total deferred tax assets	38,009	31,308
Deferred tax liabilities:		
Right-of-use asset	(4,043)	—
Unrealized gain on investments	—	(394)
Other	—	(98)
Total deferred tax liabilities	(4,043)	(492)
Less: valuation allowance:	(33,966)	(30,816)
Net deferred tax asset	$ —	$ —

The Company operates in multiple jurisdictions. Accordingly, the Company files U.S. federal and state 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 United States or in its foreign jurisdictions to realize the full benefits of its deferred tax assets. As of December 31, 2019, the Company continues to maintain a full valuation allowance against all net deferred tax assets.

The cumulative amount of earnings of our foreign subsidiaries are expected to be permanently invested in the foreign subsidiaries. Deferred taxes have not been provided on the excess of book basis over tax basis, or the excess tax basis over book basis in the shares of our foreign subsidiaries because these basis differences are not expected to reverse in the foreseeable future and are essentially permanent in duration. Our intention is to reinvest the earnings of the foreign subsidiaries indefinitely.

The increase in the valuation allowance of deferred tax assets of $3.2 million was primarily influenced by the operating losses generated in current tax year.

As of December 31, 2019, the Company had net operating loss carryforwards for U.S. federal income tax purposes of $20.1 million and net operating loss carryforwards for state income tax purposes of $26.7 million. Federal tax loss carryforwards that were created prior to December 31, 2017 expire through 2037, U.S. federal created after that date do not expire. State loss carryforwards expire starting in 2035. In the United States, utilization of the NOL carryforwards may be subject to a substantial annual limitation under Section 382 of the Code and similar state provisions 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 of the U.S. entity in 2014. Since the Company has incurred net operating losses since inception, it has never been subject to a revenue agent review. The Company is currently open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for the tax years ended 2016 through 2019. Carryforward tax attributes generated in years past may still be adjusted upon future examination if they have or will be used in a future period. The Company is currently under examination in Germany for 2014 through 2017; however, the Company not under examination by the Internal Revenue Service or any other jurisdictions for any tax years.

As of December 31, 2019, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately $90.5 million and $89.7 million respectively. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) $1.2 million plus 60% of the exceeding taxable income and trade profit of such period and do not expire. 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 accounts for uncertain tax positions pursuant to ASC 740, *Income Taxes*, 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, 2019 and December 31, 2018.

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, 2019 and 2018 (in thousands):

Unrecognized tax benefits at December 31, 2018	$	6,157
Currency translation adjustment		(125)
Unrecognized tax benefits at December 31, 2019	$	6,032

The Company does not expect unrecognized tax benefits to change significantly over the next 12 months. The full amount of unrecognized tax benefits would impact the effective rate, subject to valuation allowance considerations, if recognized.

8. Stockholders' equity

Common Stock

During the year ended December 31, 2019, the Company issued 279,075 shares of common stock upon exercise of stock options, resulting in cash proceeds of $0.6 million. During the year ended December 31, 2018, the Company issued 596,269 shares of common stock upon exercise of stock options, resulting in cash proceeds of $1.0 million.

During the year ended December 31, 2019, the Company issued 176,071 net shares of common stock due to warrant exercises. Net exercises of 127,065 shares of common stock underlying the warrants resulted in the issuance of 52,833 shares of common stock. Additionally, 123,238 warrants were exercised resulting in cash proceeds of $0.2 million. During the year ended December 31, 2018, the Company issued 156,888 shares of common stock due to warrant exercises, resulting in cash proceeds of $0.3 million. The Company had no such net issuances of common stock due to warrant exercises during the year ended December 31, 2018.

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.

Series A Preferred Stock

In June 2016, the Company entered into a securities purchase agreement, or the Securities Purchase Agreement, for a private placement of the Company’s securities with a select group of institutional investors, or 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, or the Series A Preferred Stock, which are convertible into one-thousand shares 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 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 Preferred Stock has a par value of $0.001 per share, has no registration or voting rights, and holders are entitled to receive dividends on a *pari passu* basis with the Company´s common stock, when, and if declared. In event of a true liquidation or winding down of the business, holders of Series A 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 Preferred Stock to the 2016 PIPE investors.

Series B Preferred Stock

On January 30, 2019, the Company and certain entities affiliated with Biotechnology Value Fund, L.P., or BVF entered into an exchange agreement pursuant to which BVF agreed to exchange an aggregate of 5,000,000 shares of the Company’s common stock owned by BVF for an aggregate of 5,000 shares of Series B Preferred Stock. On January 31, 2019, the Company designated 5,000 shares of its authorized and unissued preferred stock as Series B Preferred Stock and filed a Certificate of Designation of Series B Convertible Preferred Stock of Pieris Pharmaceuticals, Inc., or the Series B Certificate of Designation, with the Nevada Secretary of State.

Each share of Series B Preferred Stock is convertible into 1,000 shares of the Company's common stock (subject to adjustment as provided in the Series B Certificate of Designation) at any time at the option of the holder, provided that the holder is prohibited from converting the Series B Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of Common Stock then issued and outstanding, or the Beneficial Ownership Limitation. The holder may reset the Beneficial Ownership Limitation to a higher or lower number, not to exceed 19.99% of the total number of common shares issued and outstanding immediately after giving effect to a conversion, upon providing written notice to the Company. Any such notice providing for an increase to the Beneficial Ownership Limitation will be effective 61 days after delivery to the Company.

In the event of the Company’s liquidation, dissolution or winding up, subject to the rights of holders of Senior Securities (defined below), holders of Series B Preferred Stock are entitled to receive a payment equal to $0.001 per share of Series B Preferred Stock before any proceeds are distributed to the holders of common stock and Junior Securities (defined below) and *pari passu* with any distributions to the holders of the previously issued Series A convertible preferred stock, or the Series A Preferred Stock, plus an additional amount equal to any dividends declared but unpaid on such shares. However, if the assets of the Company are insufficient to comply with the preceding sentence, then all remaining assets of the Company shall be distributed ratably to holders of the shares of the Series B Preferred Stock and Parity Securities (defined below).

Shares of Series B Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series B Preferred Stock is required to amend the terms of the Series B Certificate of Designation. Holders of Series B Preferred Stock are entitled to receive any dividends payable to holders of the Company's common stock and rank:

- senior to all of the Company's common stock;
- senior to any class or series of capital stock of the Company created after the designation of the Series B Preferred Stock specifically ranking by its terms junior to the Series B Preferred Stock, or the Junior Securities;

- on parity with all shares of Series A Preferred Stock and any class or series of capital stock of the Company created after the designation of the Series B Preferred Stock specifically ranking by its terms on parity with the Series B Preferred Stock, or the Parity Securities; and
- junior to any class or series of capital stock of the Company created after the designation of the Series B Preferred Stock specifically ranking by its terms senior to the Series B Preferred Stock, or the Senior Securities;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily and/or the right to receive dividends.

2019 Private Placement

In November 2019, the Company entered into a securities purchase agreement for a private placement, or the Purchase Agreement with a select group of institutional investors, including lead investor BVF as well as existing and new investors, or Investors. At the time of entering into the Purchase Agreement, BVF was a more than 5% stockholder of the Company, holding shares of common stock, Series A Preferred Stock, Series B Preferred Stock and warrants to purchase shares of common stock.

The private placement consisted of 9,014,960 units, at a price of $3.55 per unit, or the Financing, for gross proceeds of approximately $32.0 million, and net proceeds to the Company of approximately $31.0 million. Each unit consists of (i) one share of the Company's common stock, or Common Shares, or 0.001 shares of non-voting Series C convertible preferred stock, or Series C Preferred Shares, and together with the Common Shares, or Shares, and (ii) one immediately-exercisable warrant to purchase one share of the Company's common stock with an exercise price of $7.10, or Exercise Price.

If (i) the initial public disclosure of the Phase 2a Study of PRS-060/AZD1402 that includes the "p" value achieved for the primary endpoint of such study reveals top-line data on the primary efficacy endpoint in the Phase 2a Study with a "p" value below 0.05 (i.e., $p < 0.05$) in at least one dose level; and (ii) the 10-day volume weighted average stock price commencing on the trading day immediately after the initial public disclosure is at least three percent more than the Exercise Price, ((i) and (ii), collectively, the "Performance Condition"), then the warrants will be exercisable for a period of 60 days from the date of the initial data disclosure and may only be exercised for cash. Otherwise, the warrants will be exercisable for a period of five years from the date of issuance, or Exercise Date. If the Performance Condition has not been met and the last reported sale price of the Company's common stock immediately prior to the Expiration Date was greater than the Exercise Price, then the warrants shall be automatically deemed exercised on a cashless basis on the Expiration Date.

Each Preferred Share is convertible into 1,000 shares of the Company's common stock. The Company will not undertake any conversion of the Series C Preferred Shares, and a stockholder shall not have the right to convert any portion of the Series C Preferred Shares, to the extent that, after giving effect to the conversion such stockholder would beneficially own in excess of 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such conversion. The holder may reset the Beneficial Ownership Limitation to a higher or lower number, not to exceed 19.99% of the total number of common shares issued and outstanding immediately after giving effect to a conversion, upon providing written notice to the Company. The Series C Preferred Shares have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series C convertible preferred stock is required to amend the terms of the Series C Certificate of Designation. The Series C 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 Series C Preferred Shares rank senior to the Company's common stock in the distribution of assets, to the extent legally available for distribution.

Upon issuance, each Series C Preferred Share included an embedded beneficial conversion feature as the market price of the Company's Common Stock on the date of issuance of the Series C convertible preferred stock was $3.43 per share. As a result, the Company recorded the intrinsic value of the beneficial conversion feature of $2.8 million as a discount on the Series C convertible preferred stock at issuance. As the Series C Preferred Shares are immediately convertible upon issuance and do not include a stated redemption date, the discount was immediately accreted as a deemed dividend.

Open Market Sale Agreement

In August 2019, the Company entered into a sale agreement pursuant to which the Company may offer and sell shares of its common stock, from time to time, up to an aggregate gross sales proceeds of $50.0 million through an "at the market offering" program under a shelf registration statement on Form S-3. To date, the Company has not sold any shares under this agreement.

9. Net Loss per Share

Basic net loss per share is calculated by dividing net income (loss) by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, preferred stock, stock options, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

For the years ended December 31, 2019 and 2018, and as calculated using the treasury stock method, approximately 33.4 million and 14.7 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

10. Stock and Employee Benefit Plans

Employee, Director and Consultant Equity Incentive Plans

At the Annual Shareholder Meeting, held on July 31, 2019, the shareholders approved the 2019 Employee, Director and Consultant Equity Incentive Plan, or the 2019 Plan. Upon approval of the 2019 Plan, the 2018 Employee, Director and Consultant Equity Incentive Plan, or the 2018 Plan, was terminated and no additional awards will be made thereunder, however, all outstanding awards under the 2018 Plan will remain in effect. The 2019 Plan, similar to the 2018 Plan, provided 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 either the Board of Directors or the compensation committee of the Board of Directors. Previously, upon approval of the 2018 Plan, the 2016 Employee, Director and Consultant Equity Incentive Plan, or the 2016 Plan, was terminated and no additional awards were made thereunder, however, all outstanding awards under the 2016 Plan remained and will continue to remain in effect. The 2016 Plan, similar to the 2014 Plan, provided 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 either the Board of Directors or the compensation committee of the Board of Directors. Previously, upon approval of the 2016 Plan, the 2014 Employee, Director and Consultant Equity Incentive Plan, or the 2014 Plan, was terminated and no additional awards were made thereunder, however, all outstanding awards under the 2014 Plan remained and continue to remain in effect.

There were approximately 654,341 shares remaining and available for grant under the 2018 Plan that terminated pursuant to the approval of the 2019 Plan. The 2019 Plan permits the Company to issue up to 5,750,000 shares, including 2,750,000 shares reserved for issuance pursuant to the 2019 Plan and up to 3,000,000 additional shares which may be issued if awards outstanding under the Registrant's 2018 Plan are canceled or expire.

The Company's stock options have a maximum term of 10 years from the date of grant. Stock options granted may be either incentive stock options or nonqualified stock options and the exercise price of stock options 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.

The Company estimates the fair value of each stock award on the grant date using the Black-Scholes option-pricing model based on the following assumptions:

	Years Ended December 31,	
	2019	2018
Risk free interest rate	1.41% - 2.60%	2.40% - 3.06%
Expected term (in years)	5.00 - 5.73	4.75 - 5.73
Dividend yield	—	—
Expected volatility	81.7% - 81.8%	77.1% - 80.5%

The weighted-average fair value of the 2,489,269 and 1,881,660 options granted during the years ended December 31, 2019 and 2018 was $2.31 and $5.04, respectively. As of December 31, 2019, there were 2,912,721 shares available for future grant under the 2019 Plan.

The following table summarizes stock option activity for employees and non-employees:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2018	6,850,047	$ 3.76		$ 3,257
Granted	2,189,269	3.16		—
Exercised	(279,075)	1.98		486
Canceled	(500,326)	4.70		288
Outstanding, December 31, 2019	8,259,915	$ 3.60	7.25 years	$ 7,987
Vested or expected to vest, December 31, 2019	8,259,915	$ 3.60	7.25 years	$ 7,987
Exercisable, December 31, 2019	4,908,300	$ 3.11	6.32 years	$ 6,348

Periodically, the Company grants inducement options, which are awards outside of approved stock option plans, and which are material awards to the executive officers or other personnel entering senior leadership roles with the Company. The terms of inducement option awards were substantially the same as those issued under our 2019 Plan. These awards are excluded from the table above. The following table summarizes stock option activity for these inducement options (in thousands):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2018	1,125,000	$ 4.41		$ —
Granted	300,000	$ 4.65		$ —
Canceled	(225,000)	$ 5.00		$ —
Outstanding, December 31, 2019	1,200,000	$ 4.36	5.93 years	$ 130
Vested or expected to vest	1,200,000	$ 4.36	5.93 years	$ 130
Exercisable, December 31, 2019	812,500	$ 4.08	4.35 years	$ 130

Employee Stock Purchase Plans

The 2018 ESPP provides eligible employees with the opportunity, through regular payroll deductions, to purchase shares of the Company's common stock at 85% of the lower closing market price of the common stock at the beginning date or ending date of each purchase period. The plan includes two six-month purchase periods per year beginning in both June and December. The Company has reserved 500,000 shares of common stock for the administration of the 2018 ESPP. Total shares purchased under the plan for the year ended December 31, 2019 were 113,112. No purchases were made under the plan for the year ended December 31, 2018. The fair value of shares expected to be purchased under the 2018 ESPP using the Black-Scholes model with the following assumptions:

	Years Ended December 31,	
	2019	2018
Risk free interest rate	1.61%	2.48%
Expected term (in years)	0.5 years	0.5 years
Dividend yield	—	—
Expected volatility	78.10%	57.57%

Total stock-based compensation expense is recorded in operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows (in thousands):

	Years Ended December 31,	
	2019	2018
Research and development	$ 2,446	$ 1,984
General and administrative	2,928	2,959
Total stock-based compensation	$ 5,374	$ 4,943

As of December 31, 2019, the total unrecognized compensation cost related to all non-vested awards was $9.3 million of which $1.2 million are for inducement options. The Company expects to recognize the compensation cost over a remaining weighted-average period of 2.46 years.

11. License Agreement

TUM License

The Company and the Technical University of Munich, or TUM, initiated discussions in the second quarter of 2018 to clarify, expand and restructure the research and licensing agreement with TUM, the TUM License, including the parties' obligations under the TUM License. The TUM License assigns or exclusively licenses to the Company certain intellectual property related to the Company's Anticalin platform technology. The parties' discussions relate to revised commercial terms and to re-initiating additional collaborations between faculty at TUM and Pieris. While an amended and restated license agreement has not yet been completed, the Company intends to enter into such an amendment. These discussions may also lead to an increase in the Company's collaborative research activities with TUM.

The Company recorded the probable expected impact of the amendment in research and development expense as of December 31, 2018, which was an increase in its financial obligations associated with the TUM License of approximately $2.3 million, for amounts that would be due in 2019 for 2018 and 2017 sub-licensing activities. This liability was paid in full during the year ended December 31, 2019.

12. Commitments and Contingencies

Leases

The Company currently leases office space in Boston, Massachusetts. In August 2015, the Company entered into a sublease to lease approximately 3,950 square feet. The sublease expires on February 27, 2022 or such earlier date pursuant to the termination provisions of the sublease.

The Company also leases approximately 19,000 square feet of office and laboratory space in Freising, Germany under four agreements, the Freising Leases, including three leases for space on three floors of the same building and a letter agreement for additional conference room space within the building. The Freising Leases all terminate on March 31, 2020.

In October 2018, Pieris GmbH entered into a new lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. Pieris GmbH moved its operations, formerly conducted in Freising, Germany, to the Hallbergmoos facility in February 2020.

Under the Hallbergmoos Lease, Pieris GmbH will rent approximately 105,000 square feet, of which approximately 96,400 square feet were delivered by the lessor in February 2020 and approximately 8,600 square feet is expected to be delivered by the lessor by May 2020. An additional approximately 22,300 square feet is expected to be delivered by the lessor by October 2024. Pieris GmbH has a first right of refusal to lease an additional approximate 13,400 square feet.

The Hallbergmoos Lease provides for an initial rental term of 12.5 years which commenced in February 2020 when the leased property was delivered to Pieris GmbH. Pieris GmbH also has an option to extend the Hallbergmoos Lease for two additional 60-month periods. The Company is not reasonably certain to exercise the option to extend the lease expiration beyond its current expiration date. Pieris GmbH may sublease space within the leased property with lessor's consent, which may not be unreasonably withheld.

Monthly base rent for the initial 105,000 square feet of the leased property, including parking spaces, will total approximately $0.2 million per month, which amount shall be adjusted starting on the second anniversary of the commencement date by an amount equal to the German consumer price index. In addition to the base rent, Pieris GmbH is also responsible for certain administrative and operational costs in accordance with the Hallbergmoos Lease. Pieris GmbH provided a security deposit of $0.8 million as of December 31, 2018. The Company will serve as a guarantor for the Hallbergmoos Lease.

The Hallbergmoos Lease included $11.5 million of tenant improvements allowance for normal tenant improvements, for which construction began in March 2019. The date of the construction coincided with the lease commencement date for accounting purposes under ASC 840, which did not change with the adoption off ASC 842. The Company capitalized the leasehold incentives which are included in Property and equipment, net on the Consolidated Balance Sheet and are amortized on a

straight-line basis over the shorter of the useful life or the remaining lease term. The lease incentive allowance was also factored in as a reduction to the right-of-use asset upon the adoption of ASC 842.

The following table summarizes operating lease costs included in operating expenses for the twelve months ended December 31, 2019 (in thousands):

	Twelve Months Ended December 31, 2019
Operating lease costs	$ 1,524
Variable lease costs (1)	293
Total lease cost	$ 1,817

(1) Variable lease costs include certain additional charges for operating costs, including insurance, maintenance, taxes, utilities, and other costs incurred, which are billed based on both usage and as a percentage of the Company's share of total square footage.

During the year ended December 31, 2018, the Company recognized rent expense in an amount of $0.5 million under the previous guidance in ASC 840.

The following table summarizes the weighted-average remaining lease term and discount rate as of December 31, 2019:

	As of December 31, 2019
Weighted-average remaining lease term (years)	12.1
Weighted-average discount rate	10.5%

Cash paid for amounts included in the measurement of the lease liabilities were $0.5 million for the twelve months ended December 31, 2019.

As of December 31, 2019, the maturities of the Company's operating lease liabilities and future minimum lease payments were as follows (in thousands):

	Total
2020	$ 2,317
2021	2,418
2022	2,249
2023	2,214
2024	2,214
Thereafter	16,790
Total undiscounted lease payments	28,202
Less: present value adjustment	(11,985)
Present value of lease liabilities	16,217

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Pieris Pharmaceuticals, Inc. ("Pieris," "we," "us" or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): Common Stock, $0.001 par value per share ("Common Stock").

DESCRIPTION OF COMMON STOCK

We are authorized to issue 300,000,000 shares of common stock, par value $0.001 per share.

The following summary of certain provisions of our common stock does not purport to be complete. This description is summarized from, and is qualified in its entirety by reference to, our amended and restated articles of incorporation and our amended and restated bylaws, to which you should refer and both of which are included as exhibits to this Form 10-K. The summary below is also qualified by provisions of applicable law, including Chapters 78 and 92A of the Nevada Revised Statutes, or NRS, as applicable to corporations.

General

The holders of our common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if declared by our Board of Directors, out of funds that we may legally use to pay dividends. All of the issued and outstanding shares of our common stock are duly authorized, validly issued, fully paid and non-assessable.

If we liquidate or dissolve, holders of our common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our amended and restated articles of incorporation do not provide our common stock with any redemption, conversion or preemptive rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of then-outstanding preferred stock.

Registration Rights

Private Placement Registration Rights

On December 17, 2014, we entered into a purchase agreement with multiple investors relating to the issuance and sale of shares of our common stock in a private placement (the "2014 Private Placement"). The 2014 Private Placement held closings on December 17, December 18, and December 23, 2014, through which we sold an aggregate of 6,779,510 shares of our common stock at $2.00 per share for aggregate proceeds of approximately $13.6 million.

We also issued warrants to acquire up to 542,360 shares of our common stock at an exercise price of $2.00 per share to placement agents or their designees (the "Placement Agent Warrants").

In connection with the 2014 Private Placement, we entered into a registration rights agreement and agreed to file a registration statement covering the resale of the shares sold in the 2014 Private Placement, the shares underlying the Placement Agent Warrants, and the 20,000,000 shares of our common stock issued to former stockholders of Pieris GmbH in connection with the share exchange transaction on December 17, 2014. We filed a registration statement on Form S-1 which was declared effective by the SEC on May 11, 2015. We have agreed to keep such registration statement effective until the later of December 17, 2016 and such time as all of the securities to be registered thereunder have been sold under the registration statement or may be sold without restriction pursuant to Rule 144.

On June 2, 2016, we entered into a securities purchase agreement with multiple investors relating to the issuance and sale of units consisting of: (i) one share of our common stock or non-voting series A convertible preferred stock convertible into one share of common stock, and (ii) a warrant to purchase 0.40 shares of our

common stock with an exercise price of $2.00 per share and (iii) a warrant to purchase 0.20 shares of our common stock with an exercise price of $3.00 per share (the "2016 Private Placement"). The 2016 Private Placement closed on June 8, 2016 and we sold 8,188,804 units for gross proceeds of approximately $16.5 million.

In connection with the 2016 Private Placement, we entered into a registration rights agreement with the investors and agreed to register the resale of the common stock, the common stock underlying the preferred stock, and the warrants. We filed a registration statement on Form S-3 which was declared effective by the SEC on August 3, 2016. We have agreed to use our commercially reasonable efforts to keep such registration statement effective until the earliest to occur of: (i) such time as all of the securities to be registered thereunder have been sold under the registration statement, (ii) such time as all of the securities to be registered thereunder may be sold without restriction pursuant to Rule 144, or (iii) June 8, 2018.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. Its address is P.O. Box 505000, Louisville, KY, 40233-5000. Their telephone number is (877) 373-6374 from the United States, Canada and Puerto Rico and (781) 575-3100 from all other locations.

Stock Exchange Listing

Our common stock is listed for quotation on the Nasdaq Capital Market, under the symbol "PIRS."

CERTAIN PROVISIONS OF DELAWARE LAW AND OF THE COMPANY'S AMENDED AND RESTATED ARTICLES OF INCORPORATION AND AMENDED AND RESTATED BYLAWS

Anti-Takeover Provisions

The provisions of Delaware law and our amended and restated articles of incorporation and amended and restated bylaws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

Delaware Statutory Business Combinations Provision

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a "business combination" is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an "interested stockholder" is a person who, together with his or her affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation's voting stock.

Classified Board of Directors; Removal of Directors for Cause

Pursuant to our amended and restated articles of incorporation and amended and restated bylaws, our board of directors is divided into three classes, with the term of office of the first class to expire at the first annual meeting of stockholders following the initial classification of directors, the term of office of the second class to expire at the second annual meeting of stockholders following the initial classification of directors, and the term of office of the third class to expire at the third annual meeting of stockholders following the initial classification of directors. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire, other than directors elected by the holders of any series of preferred stock under specified circumstances, will be elected for a three-year term of office. All directors elected to our classified board of

directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. Members of the board of directors may only be removed for cause and only by the affirmative vote of at least 80% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the board of directors. For example, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the board of directors.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors

Our amended and restated bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 90 days nor more than 120 days prior to the first anniversary of the previous year's annual meeting date. For a special meeting, the notice must generally be delivered not earlier than the 90th day prior to the meeting and not later than the later of (1) the 60th day prior to the meeting or (2) the 10th day following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the amended and restated bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaw provisions, such business will not be conducted at the meeting.

Special Meetings of Stockholders

Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

No Stockholder Action by Written Consent

Any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders.

Super Majority Stockholder Vote Required for Certain Actions

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's articles of incorporation or bylaws, unless the corporation's articles of incorporation or bylaws, as the case may be, require a greater percentage. Our amended and restated articles of incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section of this Exhibit. This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. An affirmative vote of the holders of at least 80% of our outstanding voting stock is also required for any amendment to, or repeal of, our amended and restated bylaws by the stockholders. Our amended and restated bylaws may be amended or repealed by a simple majority vote of the board of directors.

PIERIS PHARMACEUTICALS GmbH
Lise-Meitner-Strasse 30
85354 Freising, Germany
Attention: Alliance Management

Copy to:
PIERIS PHARMACEUTICALS Inc.
255 State Street, 9th Floor
Boston, MA 02109
Attention: Legal Counsel

February 5, 2020

By email and by registered letter with acknowledgement of receipt

Re: Letter to extend the Initial Research Collaboration Term pursuant to section 3.1.1 a) of the License and Collaboration Agreement between Les Laboratoires Servier and Institut de Recherches Internationales Servier (individually and collectively "***Servier***") and Pieris Pharmaceuticals Inc. and Pieris Pharmaceuticals GmbH (individually and collectively "***Pieris***") ("Servier" and "Pieris" collectively the **"*Parties*"**) dated January 4, 2017 referenced 162756/SNET/PTCE as amended (the "***Agreement***")

Dear Sirs,

The Initial Research Collaboration Term expires on January 3rd, 2020 in accordance with section 1.124 of the Agreement.

In that respect, Servier and Pieris mutually agree by the present letter (the "***Letter Amendment***") to extend the Initial Research Collaboration Term for the Initial Collaboration Products which are still under Development under the applicable Collaboration Plans and which have not reached PCC yet [***] by one (1) year (the "***Initial Research Collaboration Renewal Term***") pursuant to section 3.1.1 a) of the Agreement. Consequently, the Initial Research Collaboration Renewal Term shall now be due to expire on January 3, 2021.

Pursuant to 3.1.6 a) the Parties agree that the additional sum to be paid to Pieris (the "***Collaboration Renewal Development Funds***") with respect to such Collaboration Renewal Term is [***]. Such Collaboration Renewal Development Funds includes (i) [***], and (ii) an additional lump sum of [***]. The Collaboration Renewal Development Funds shall be paid in quarterly installments of [***] following receipt of invoices requesting such payments, with the first payment due within forty-five (45) days of the execution of this Letter Amendment, the second payment due within forty-five (45) days of April 1, 2020, the third payment due within forty-five (45) days of July 1, 2020 and the fourth payment due within forty-five (45) days of October 1, 2020.

Following extension of the Initial Research Collaboration Term, the Parties mutually agree to update by this Letter Amendment the applicable Collaboration Plans and Collaboration Budgets accordingly. The updated versions of the Collaboration Plans and Collaboration Budgets are attached as exhibits to this Letter Amendment and may be updated or amended from time-to-time pursuant to the Agreement.

Capitalized terms or derivatives thereof when used herein shall have the meaning attributed to them in the Agreement.

This Letter Amendment does not modify the Agreement on any aspects other than those explicitly stated herein. All other provisions of the Agreement not modified by this Letter Amendment shall remain in full force and effect.

This Letter Amendment, comprising three (3) exhibits, is made in four (4) original copies and shall become effective as of January 3, 2020.

Please provide acknowledgement of this Letter Amendment, by having this Letter Amendment signed by a duly-authorized signatory and **returning two (2) executed copy** of this Letter Amendment at your earliest convenience to Mr. Romuald LAINE (at Institut de Recherches Internationales Servier, 50 rue Carnot, 92284 Suresnes Cedex, France) with an electronic copy to romuald.laine@servier.com.

Yours sincerely,

For INSTITUT DE RECHERCHES INTERNATIONALES SERVIER

By: /s/ Dr. Claude Bertrand

Name : Dr. Claude Bertrand
Title: Vice-President Research and Development

For LES LABORATOIRES SERVIER

By: /s/ Mr. Christian Bazantay

Name: Mr. Christian BAZANTAY
Title: Proxy

By: /s/ Mr. Eric Falcand

Name: Mr. Eric FALCAND
Title: Proxy

For PIERIS PHARMACEUTICALS, INC.	For PIERIS PHARMACEUTICALS GMBH
By: /s/ Stephen S. Yoder	By: /s/ Stephen S. Yoder
Name : Stephen Yoder Title: CEO	Name : Stephen Yoder Title: Managing Director

Exhibit 3.1.2. (a)2

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 3.1.2. (a)3

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 3.1.2. (a)4

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Summary

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.25

255 State Street, 9th Floor
Boston, MA 02109

January 3, 2020

VIA EMAIL

Louis Matis, M.D.

Re: Separation Agreement

Dear Louis:

The purpose of this letter agreement (the "**Agreement**") is to set forth the terms of your separation from Pieris Pharmaceuticals, Inc. ("**Pieris**" or the "**Company**"). Payment of the Separation Benefit described below is contingent on your agreement to and compliance with the terms of this Agreement. This Agreement shall become effective on the date that is the **eighth (8th) day** following your execution of it, as explained more fully in Section 6 below (the "Effective Date").

1. Separation of Employment. As we discussed, your employment with Pieris shall terminate effective January 10, 2020 (the "**Separation Date**"). As of the Separation Date, all salary payments from the Company shall cease and any benefits you currently have under Company-provided benefit plans, programs, or practices shall terminate, except as required by federal or state law or as otherwise set forth herein. The Company shall provide you with all wages owed through the Separation Date, and shall pay all normal and reasonable business expenses that you have incurred or shall incur in the ordinary course through the Separation Date. Receipts for any outstanding business expenses shall be submitted within ten (10) days of the Separation Date. You shall not represent yourself as an employee of Pieris after the Separation Date. By executing this Agreement, you hereby resign from any other positions, offices or directorships you may have with the Company or any of its subsidiaries or affiliates.

2. Separation Benefit. In exchange for the promises and covenants contained herein, your compliance with the terms of your Employment Agreement dated July 20, 2015 (the "**Employment Agreement**") and this Agreement, and your execution and non-revocation of the Release of Claims attached as Exhibit A (the "**Release**"), Pieris agrees to provide you with the following:

(a) Severance Payments. Pieris shall provide you with (i) severance pay in the form of continued payment of your gross Base Salary (as defined in your Employment Agreement), less applicable withholdings and deductions, for a period of six (6) months, payable in bi-monthly installments commencing with the Company's first payroll date following the effective date of the Release; and (ii) a payment for your 2019 annual discretionary bonus, in the form of one (1) lump-

sum payment, less applicable withholdings and deductions, to be determined and paid with and at the same time as all other employees at the end of February.

(b) Vesting of Options.

i. Pieris shall accelerate the vesting of 75% of your issued but unvested stock options issued pursuant to any stock option grants, and such stock options shall be vested and exercisable as of the effective date of the Release in accordance of the terms of the applicable option agreement.

ii. You acknowledge and agree that the remaining 25% of all unvested stock options are hereby terminated as of the Separation Date, and you shall have no right(s) to exercise any portion of such stock options following the Separation Date. You acknowledge and agree that the Company does not guarantee or make any representations regarding the tax consequences or tax treatment of any vested stock options. Except as modified herein, the terms and conditions of each stock option agreement entered with you are incorporated herein by reference and shall survive the signing of this Agreement.

(c) Continued Healthcare. By law, and regardless of whether you sign this Agreement, you shall have the right to continue your medical and dental insurance pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"). The COBRA qualifying event shall be deemed to have occurred on January 10, 2020. Upon completion of the appropriate COBRA forms and your execution of this Agreement, and subject to all the requirements of COBRA, you shall be allowed to continue participation in the Company's health and dental insurance plans at the Company's expense (except for your co-pay or your portion of premium payments, if any, which shall be paid directly by you), for the period commencing on the first day of the full calendar month following the effective date of the Release and irrevocable through the earlier of (i) the last day of the six (6) full calendar months following the effective date of the Release and (ii) the date you and your covered dependents, if any, become eligible healthcare coverage under another employer's plan(s). You agree to provide the Company with written notice immediately upon securing such employment and upon becoming eligible for such benefits. Thereafter, your eligibility to continue participation in the Company's health and dental insurance plans under COBRA (including but not limited to the COBRA premium payments required for same) shall be subject to COBRA rules and provisions.

The payments and benefits provided under this Section 2 shall be referred to as the "Separation Benefit." You acknowledge and agree that the Separation Benefit is not otherwise due or owing to you under any Pieris policy or practice. For the avoidance of doubt, the above-described Separation Benefit shall be in lieu of (and not in addition to) any payments or benefits described in Section 4(b) of the Employment Agreement. You further acknowledge that except for the Separation Benefit, your final wages, any accrued but unused vacation, and any properly incurred but not yet reimbursed business expenses (each of which shall be paid or reimbursed, as the case may be, in accordance with Pieris' regular payroll practices and applicable law), you are not now and shall not in the future be entitled to any other compensation from Pieris including, without limitation, other wages, commissions, bonuses, vacation pay, holiday pay, equity, stock, stock options, paid time off, or any other form of compensation or benefit.

3. Cooperation. You shall cooperate fully with Pieris in connection with any matter or event relating to your employment or events that occurred during your employment, including,

without limitation: **(a)** being available upon reasonable notice to meet with Pieris regarding matters in which you have been involved; **(b)** assisting Pieris in transitioning your job duties to other Pieris personnel or contractors; **(c)** assisting with any audit, inspection, proceeding or other inquiry by a private or public entity; and **(d)** as requested by Pieris, assisting in the defense or prosecution of any claims or actions now in existence or which may be brought or threatened in the future against or on behalf of Pieris (including claims or actions against its affiliates and its and their officers and employees), including acting as a witness, providing affidavits, and preparing for, attending and participating in any legal proceeding (including depositions, consultation, discovery or trial) in connection with such claim or action. You further agree that should you be contacted (directly or indirectly) by any person or entity (for example, by any party representing an individual or entity) adverse to the Company, you shall promptly notify the President and Chief Executive Officer of the Company. You shall be reimbursed for any reasonable out-of-pocket costs and expenses approved in advance by Pieris and incurred in connection with providing such cooperation under this Section 3.

4. Your Additional Covenants. You expressly acknowledge and agree to the following:

(a) You shall adhere to the ongoing obligations in your Employment Agreement (including, but not limited to, Section 4(a)), the Corporate Code of Conduct and Ethics, Whistleblower Policy and Insider Trading Policy, and any other agreements between you and the Company regarding confidential information, intellectual property, and non-competition and non-solicitation (the "**Agreements**"), the terms of which are incorporated herein and shall survive the signing of this Agreement.

(b) You shall promptly return to the Company or destroy all Company documents (and any copies thereof), equipment and property, and you shall abide by any and all common law and statutory obligations relating to protection of the Company's trade secrets and confidential and proprietary information.

(c) In the event that you receive an order, subpoena, request, or demand for disclosure of the Company's trade secrets and/or confidential and proprietary documents and information from any court or governmental agency, or from a party to any litigation or administrative proceeding, you shall notify the Company of same as soon as reasonably possible and prior to disclosure, in order to provide the Company with the opportunity to assert its respective interests in addressing or opposing such order, subpoena, request, or demand.

(d) All information relating in any way to the negotiation of this Agreement, including the terms and amount of financial consideration provided for in this Agreement, shall be held confidential by you and shall not be publicized or disclosed to any person (other than an immediate family member, legal counsel or financial advisor, provided that any such whom disclosure is made agrees to be bound by these confidentiality obligations), to any government agency (except as mandated by state or federal law), or to any business entity.

(e) You shall not make any statements that are disparaging about the Company or its officers, directors, managers or employees, including, but not limited to, any statements that disparage any program, service, finances, financial condition, capability or any other aspect of the business of the Company, and you shall not engage in any conduct which is intended to harm professionally or personally the reputation of the Company or its officers, directors, managers or employees.

(f) A breach of any provision of this Section 4 shall constitute a material breach of this Agreement and, in addition to any other legal or equitable remedy available to the Company, shall entitle the Company to recover the Separation Benefit provided to you under this Agreement.

5. Your Release of Claims.

(a) Release. You hereby agree that by signing this Agreement and accepting the Separation Benefit and other good and valuable consideration provided for in this Agreement, you are waiving and releasing your right to assert any form of legal claim against the Company[1/] whatsoever for any alleged action, inaction or circumstance existing or arising from the beginning of time through the Effective Date. Your waiver and release herein is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "Claims") against the Company seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against the Company, for any alleged action, inaction or circumstance existing or arising through the Effective Date. Without limiting the foregoing general waiver and release, you specifically waive and release the Company from any Claim arising from or related to your employment relationship with the Company or the termination thereof, including, without limitation:

(i) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to employment, discrimination, fair employment practices, or other terms and conditions of employment, including but not limited to the Age Discrimination in Employment Act and Older Workers Benefit Protection Act (29 U.S.C. § 621 et seq.), the Civil Rights Acts of 1866 and 1871 and Title VII of the Civil Rights Act of 1964 and the Civil Rights Act of 1991 (42 U.S.C. § 2000e et seq.), the Equal Pay Act (29 U.S.C. § 201 et seq.), the Americans With Disabilities Act (42 U.S.C. § 12101 et seq.), the Genetic Information Non-Discrimination Act (42 U.S.C. §2000ff et seq.), the Massachusetts Fair Employment Practices Statute (M.G.L. c. 151B § 1 et seq.), the Massachusetts Equal Rights Act (M.G.L. c. 93 §102), the Massachusetts Civil Rights Act (M.G.L. c. 12 §§ 11H & 11I), the Massachusetts Privacy Statute (M.G.L. c. 214 § 1B), the Massachusetts Sexual Harassment Statute (M.G.L. c. 214 § 1C), and any similar Massachusetts or other state or federal statute.

(ii) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to leaves of absence, layoffs or reductions-in-force, wages, hours, or other terms and conditions of employment, including but not limited to the National Labor Relations Act (29 U.S.C. § 151 et seq.), the Family and Medical Leave Act (29 U.S.C. §2601 et seq.), the Employee Retirement Income Security Act of 1974 (29 U.S.C. § 1000 et seq.), COBRA (29 U.S.C. § 1161 et seq.), the Worker Adjustment and Retraining Notification Act (29 U.S.C. § 2101 et seq.), the Uniformed Services Employment and Reemployment Rights Act of 1994 (38 U.S.C. § 4301 et seq.), the Massachusetts Wage Act (M.G.L. c. 149 § 148 et. seq.), the Massachusetts Minimum Fair Wages Act (M.G.L. c. 151 § 1 et. seq.), the Massachusetts Equal Pay Act (M.G.L. c. 149 § 105A), and any similar Massachusetts or other state or federal statute. *Please note that this section specifically includes a waiver and release of Claims that you have or may have regarding payments or amounts covered by the Massachusetts Wage Act or the Massachusetts Minimum Fair Wages Act (including, for instance,*

1/ For the purposes of this Section 5, the parties agree that the term "Company" shall include Pieris Pharmaceuticals, Inc., its divisions, affiliates, parents and subsidiaries, and any of its and their respective officers, directors, shareholders, employees, consultants, contractors, attorneys, agents and assigns.

hourly wages, salary, overtime, minimum wages, commissions, vacation pay, holiday pay, sick leave pay, dismissal pay, bonus pay or severance pay), as well as Claims for retaliation under the Massachusetts Wage Act or the Massachusetts Minimum Fair Wages Act.

(iii) Claims under any state or federal common law theory, including, without limitation, wrongful discharge, breach of express or implied contract, promissory estoppel, unjust enrichment, breach of a covenant of good faith and fair dealing, violation of public policy, defamation, interference with contractual relations, intentional or negligent infliction of emotional distress, invasion of privacy, misrepresentation, deceit, fraud or negligence or any claim to attorneys' fees under any applicable statute or common law theory of recovery.

(iv) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to violation of public policy or any other form of retaliation or wrongful termination, under any federal or any similar Massachusetts or other state or federal statute.

(v) Claims under any Company employment, compensation, benefit, stock option, incentive compensation, bonus, restricted stock, and/or equity plan, program, policy, practice or agreement, including, without limitation the Employment Agreement and the Option Agreement.

(vi) Any other Claim arising under any other state or federal law.

You explicitly acknowledge that because you are over forty (40) years of age, you have specific rights under the ADEA, which prohibits discrimination on the basis of age, and that the releases set forth in this Section 5 are intended to release any right that you may have to file a claim against the Company alleging discrimination on the basis of age.

(b) Release Exclusions. Notwithstanding the foregoing, this Section 5 does not: (i) release the Company from any obligation expressly set forth in this Agreement or from any obligation, including without limitation obligations under the Workers Compensation laws, which as a matter of law cannot be released or any applicable option agreement; (ii) release any right to indemnification under the Company's Bylaws, Articles of Incorporation, and/or directors' and officers' liability insurance policies as of the Separation Date, subject to the terms and conditions of same (iii) prohibit you from filing a charge with the Equal Employment Opportunity Commission ("EEOC"), the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, or any other federal, state or local governmental agency or commission (a "Government Agency"); (iv) prohibit you from participating in an investigation or proceeding by a Government Agency, communicating with a Government Agency, or providing information or documents to a Government Agency; or (v) prohibit you from challenging or seeking a determination in good faith of the validity of this release or waiver under applicable state or federal law, or impose any condition precedent, penalty, or costs for doing so unless specifically authorized by state or federal law. Your waiver and release, however, are intended to be a complete bar to any recovery or personal benefit by or to you with respect to any claim whatsoever, including those raised through a charge with the EEOC or comparable federal, state or local governmental agency, except those which, as a matter of law, cannot be released.

(c) Acknowledgment. You acknowledge and agree that, but for providing this waiver and release, and for providing the Release, you would not be receiving the Separation Benefit being provided to you under the terms of this Agreement. You further agree that should you breach this Section 5 or the Release, the Company, in addition to any other legal or equitable

remedy available to the Company, shall be entitled to recover any the cost of the Separation Benefit previously provided to you pursuant to Section 2 hereof.

6. **ADEA/OWBPA Review and Revocation Period. You and Pieris acknowledge that you are over the age of 40 and that you, therefore, have specific rights under the Age Discrimination in Employment Act ("ADEA") and the Older Workers Benefit Protection Act (the "OWBPA"), which prohibit discrimination on the basis of age. It is Pieris' desire and intent to make certain that you fully understand the provisions and effects of this Agreement. To that end, you have been encouraged and given the opportunity to consult with legal counsel for the purpose of reviewing the terms of this Agreement. Consistent with the provisions of the ADEA and OWBPA, Pieris also is providing you with twenty one (21) days in which to consider and accept the terms of this Agreement by signing below and returning it to Stephen S. Yoder, President and Chief Executive Officer, Pieris Pharmaceuticals, Inc., 255 State Street, 9th Floor, Boston, MA 02129. You agree that any modifications, material or otherwise, made to this Agreement do not and shall not restart or affect in any manner whatsoever, the original 21-day Review Period. You may rescind your assent to this Agreement if, within seven (7) days after you sign this Agreement, you deliver by hand or send by mail (certified, return receipt and postmarked within such 7-day period) a notice of rescission at the above-referenced address.**

7. **Opportunity to Disclose.** You acknowledge that you have been provided the opportunity to advise the Company as to any concerns regarding its financial statements, SEC filings and other public disclosures or any other matters, and have confirmed to the Company that you have no such concerns.

8. **Taxes and Withholdings.** The Separation Benefit provided under this Agreement shall be reduced by all applicable federal, state, local and other deductions, taxes, and withholdings. Pieris does not guarantee the tax treatment or tax consequences associated with any payment or benefit under this Agreement, including but not limited to consequences related to Section 409A of the Code.

9. **Modification; Waiver; Severability.** No variations or modifications hereof shall be deemed valid unless reduced to writing and signed by the parties hereto. The failure of Pieris to seek enforcement of any provision of this Agreement in any instance or for any period of time shall not be construed as a waiver of such provision or of Pieris' right to seek enforcement of such provision in the future. The provisions of this Agreement are severable, and if for any reason any part hereof shall be found to be unenforceable, the remaining provisions shall be enforced in full.

10. **Choice of Law and Venue; Jury Waiver.** This Agreement shall be deemed to have been made in Massachusetts, shall take effect as an instrument under seal within Massachusetts, and shall be governed by and construed in accordance with the laws of Massachusetts, without giving effect to conflict of law principles. You agree that any action, demand, claim or counterclaim relating to the terms and provisions of this Agreement, or to its breach, shall be commenced in Massachusetts in a court of competent jurisdiction, and you further acknowledge that venue for such actions shall lie exclusively in Massachusetts and that material witnesses and documents would be located in Massachusetts.

11. **Entire Agreement.** You acknowledge and agree that this Agreement and the Release , along with the specific agreements that are expressly incorporated herein by reference and stated as surviving the signing of this Agreement, supersede any and all prior or

contemporaneous oral and written agreements between you and Pieris, and set forth the entire agreement between you and Pieris.

12. Knowing and Voluntary Agreement. By executing this Agreement, you are acknowledging that you have been afforded sufficient time to understand the terms and effects of this Agreement, that your agreements and obligations hereunder are made voluntarily, knowingly and without duress, and that neither Pieris nor its agents or representatives have made any representations inconsistent with the provisions of this Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

This Agreement may be signed on one or more copies, each of which when signed shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. If the foregoing correctly sets forth our understanding, please sign, date and return the enclosed copy of this Agreement to me. If Pieris does not receive your acceptance within **twenty-one (21) days**, the Agreement shall terminate and be of no further force or effect.

Sincerely,

PIERIS PHARMACEUTICALS, INC.

DocuSigned by:

By: _____
75486A6C0DAF4FE...

Stephen S. Yoder
President and Chief Executive Officer

Dated: 1/3/2020

Agreed and Acknowledged:

DocuSigned by:

_____
14AA0BD7EFE24DF...

Louis Matis, MD

Dated: 1/3/2020

EXHIBIT A

RELEASE OF CLAIMS

In consideration of the covenants set forth in my letter agreement with Pieris Pharmaceuticals, Inc. (the "Company") dated January 3, 2020 (the "Separation Agreement"), and more particularly the payments provided to me in the Separation Agreement and other good and valuable consideration, I, Louis Matis, waive and release my right to assert any form of legal claim against the Company[2/] whatsoever for any alleged action, inaction or circumstance existing or arising from the beginning of time through the effective date of this Release . My waiver and release herein is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "Claims") against the Company seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against the Company, for any alleged action, inaction or circumstance existing or arising through the effective date of this Release. Without limiting the generality of the foregoing waiver and release of claims, I specifically waive and release the Company from any Claim arising from or related to my employment relationship with the Company or the termination thereof including, without limitation:

(a) Claims under any state or federal statute, regulation or executive order (as amended) relating to employment, discrimination, fair employment practices, or other terms and conditions of employment, including but not limited to the Age Discrimination in Employment Act and Older Workers Benefit Protection Act, the Civil Rights Acts of 1866 and 1871 and Title VII of the Civil Rights Act of 1964 and the Civil Rights Act of 1991, the Equal Pay Act, the Americans With Disabilities Act, the Genetic Information Non-Discrimination Act, the Massachusetts Fair Employment Practices Statute, the Massachusetts Equal Rights Act, the Massachusetts Civil Rights Act, the Massachusetts Privacy Statute, the Massachusetts Sexual Harassment Statute, and any similar Massachusetts or other state or federal statute.

(b) Claims under any state or federal statute, regulation or executive order (as amended) relating to leaves of absence, layoffs or reductions-in-force, wages, hours, or other terms and conditions of employment, including but not limited to the National Labor Relations Act, the Family and Medical Leave Act, the Employee Retirement Income Security Act of 1974, the Worker Adjustment and Retraining Notification Act, the Uniformed Services Employment and Reemployment Rights Act of 1994, the Massachusetts Wage Act, the Massachusetts Minimum Fair Wages Act, the Massachusetts Equal Pay Act, and any similar Massachusetts or other state or federal statute. *This section specifically includes a waiver and release of Claims that I have or may have regarding payments or amounts covered by the Massachusetts Wage Act or the Massachusetts Minimum Fair Wages Act (including, for instance, hourly wages, salary, overtime, minimum wages, commissions, vacation pay, holiday pay, sick leave pay, dismissal pay, bonus pay or severance pay), as well as Claims for retaliation under the Massachusetts Wage Act or the Massachusetts Minimum Fair Wages*

2/ For the purposes of this Supplemental Release, the term "Company" shall include Pieris Pharmaceuticals, Inc., its divisions, affiliates, parents and subsidiaries, and any of its and their respective officers, directors, shareholders, employees, consultants, contractors, attorneys, agents and assigns.

Act.

(c) Claims under any state or federal common law theory, including, without limitation, wrongful discharge, breach of express or implied contract, promissory estoppel, unjust enrichment, breach of a covenant of good faith and fair dealing, violation of public policy, defamation, interference with contractual relations, intentional or negligent infliction of emotional distress, invasion of privacy, misrepresentation, deceit, fraud or negligence or any claim to attorneys' fees under any applicable statute or common law theory of recovery.

(d) Claims under any state or federal statute, regulation or executive order (as amended through the Effective Date) relating to whistleblower protections, violation of public policy, or any other form of retaliation or wrongful termination, including but not limited to the Sarbanes-Oxley Act of 2002 and any similar Massachusetts or other state or federal statute.

(e) Claims under any Company employment, compensation, benefit, stock option, incentive compensation, bonus, restricted stock, and/or equity plan, program, policy, practice or agreement, including without limitation, my Employment Agreement and Option Agreement.

(f) Any other Claim arising under any other state or federal law.

This Release does not: (i) release the Company from any obligation expressly set forth in my Separation Agreement or from any obligation, including without limitation obligations under the Workers Compensation laws, which as a matter of law cannot be released; (ii) release any right to indemnification under the Company's Bylaws, Articles of Incorporation, and/or directors' and officers' liability insurance policies as of the Separation Date, subject to the terms and conditions of same (iii) prohibit me from filing a charge with the Equal Employment Opportunity Commission ("EEOC"), the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, or any other federal, state or local governmental agency or commission (a "Government Agency"); (iv) prohibit me from participating in an investigation or proceeding by a Government Agency, communicating with a Government Agency, or providing information or documents to a Government Agency; or (v) prohibit me from challenging or seeking a determination in good faith of the validity of this release or waiver under applicable state or federal law, or impose any condition precedent, penalty, or costs for doing so unless specifically authorized by state or federal law. My waiver and release, however, are intended to be a complete bar to any recovery or personal benefit with respect to any claim whatsoever, including those raised through a charge with the EEOC or comparable federal, state or local governmental agency, except those which, as a matter of law, cannot be released.

I acknowledge that I have been encouraged and given the opportunity to consult with legal counsel for the purpose of reviewing the terms of this Release, which includes a release of claims based on age under the ADEA. The Company also is providing me with **twenty-one (21) days** in which to consider and accept the terms of this Release by signing below and returning it to Steven S. Yoder. I agree that any modifications, material or otherwise, made to this Release do not and shall not restart or affect in any manner whatsoever, the original 21-day Review Period. In addition, I may rescind my assent to this Release within **seven (7) days** after I sign it. To do so, I must deliver a notice of rescission to Steven S. Yoder. To be effective, such rescission must

be hand delivered or postmarked within such **7-day period** and sent by certified mail, return receipt requested, to Steven S. Yoder at the address above.

I expressly acknowledge and agree that, but for providing the foregoing Release, I would not be receiving the consideration being provided to me under the terms of the Separation Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

This Release may be signed and returned to Stephen S. Yoder any time within 21 days following the Separation Date, but **not** before the Separation Date. This Release shall become effective on the eighth (8th) day following the date that I sign below.

Confirmed and Agreed:

DocuSigned by:
Louis Matis
E3684C85CAB749F...

Louis Matis, MD

Dated: January 15, 2020

Pieris Pharmaceuticals, Inc.

By: _____

Stephen S. Yoder
President and Chief Executive Officer

Dated: January 15, 2020

Exhibit 10.26

PIERIS PHARMACEUTICALS, INC.

AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Board of Directors of Pieris Pharmaceuticals, Inc. (the "Company") has approved the following Amended and Restated Non-Employee Director Compensation Policy (this "Policy") which establishes compensation to be paid to non-employee directors of the Company, effective as of December 30, 2019 ("Effective Time"), to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

Applicable Persons

This Policy shall apply to each director of the Company who is not an employee of the Company or any Affiliate (each, a "Non-Employee Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

Stock Option Grants

All stock option amounts set forth herein shall be subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock, par value $0.001 per share (the "Common Stock").

Interim Stock Option Grant

On January 25, 2020, (i) each Non-Employee Director shall be automatically granted a non-qualified stock option to purchase 20,000 shares of Common Stock under the Company's then-current Stock Incentive Plan, as of the Effective Time the 2018 Stock Incentive Plan (the "Stock Plan"), and (ii) the Chairperson of the Board of Directors (the "Chairperson") shall be automatically granted an additional non-qualified stock option to purchase 2,500 shares of Common Stock under the Stock Plan (together, the "Interim Director Awards").

Annual Stock Option Grants

Beginning in calendar 2020, each calendar year, (i) each Non-Employee Director shall be automatically granted a non-qualified stock option to purchase 40,000 shares of Common Stock under the Stock Plan on the date of the annual meeting of the Board of Directors coincident with or immediately following the Company's annual meeting of stockholders (the "Annual Stockholders Meeting"), and (ii) the Chairperson shall be automatically granted an additional non-qualified stock option to purchase 5,000 shares of Common Stock under the Stock Plan (together, the "Annual Director Awards"). To the extent that the Non-Employee Director or Chairperson, as applicable, has served in that position for less than one year, then the Annual Director Award shall be pro-rated with respect to such Non-Employee Director or Chairperson.

Initial Stock Option Grant for Newly Appointed or Elected Directors and Chairperson

Each new Non-Employee Director shall be automatically granted a non-qualified stock option to purchase 30,000 shares of Common Stock under the Stock Plan at the first regularly scheduled meeting of the Board of Directors on or after his or her initial appointment or election to the Board of Directors (the "Initial Director Award"). The Chairperson shall be automatically granted an additional non-qualified stock option to purchase 40,000 shares of Common Stock under the Stock Plan at the first regularly scheduled meeting of the Board of Directors on or after his or her initial appointment or election as Chairperson (the "Initial Chairperson Award").

Terms for All Option Grants

Unless otherwise specified in this Policy or by the Board of Directors or the Compensation Committee at the time of grant, all options granted under this Policy shall: (i) vest, in the case of (A) the Annual Director Awards, at the end of the "Directors' Compensation Year", which shall be defined as the approximately one-year period beginning on the date of each regular Annual Stockholders Meeting and ending on the date of the next regular Annual Stockholders Meeting, subject to the Non-Employee Director's continued service on the Board of Directors through the applicable Directors' Compensation Year, and (B) the Interim Director Awards and the Initial Director Award, one (1) year after the date of grant of such option, subject to the Non-Employee Director's continued service on the Board of Directors on the vesting date, and (C) the Initial Chairperson Award, as to twenty-five percent (25%) of the shares underlying the Initial Chairperson Award on the first anniversary of the date of the Chairperson's appointment or election as Chairperson (the "Initial Vesting Date"), with the remaining seventy-five percent (75%) of the shares underlying the Initial Chairperson Award vesting in twelve (12) equal quarterly installments at the end of each full calendar quarter following the Initial Vesting Date, subject to the Chairperson's continued service as Chairperson on the vesting date; (ii) have an exercise price equal to the fair market value of the Common Stock on the grant date, as determined in the Stock Plan; (iii) terminate ten years after the grant date; and (iv) contain such other terms and conditions as set forth in the form of option agreement approved by the Board of Directors or the Compensation Committee prior to the grant date.

Annual Fees

Each Non-Employee serving on the Board of Directors and the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, and/or Science and Technology Committee, as applicable, shall be entitled to the following annual amounts (the "Annual Fees"):

Board of Directors or Committee of Board of Directors	**Annual Retainer Amount for Member**	**Annual Retainer Amount for Chair**
Board of Directors	$35,000	$30,000*
Audit Committee	$7,500	$15,000**
Science and Technology Committee	$5,000	$10,000**

Compensation Committee	$5,000	$10,000**
Nominating and Corporate Governance Committee	$4,000	$8,000**

* The annual retainer amount for the Chair of the Board of Directors is in addition to the annual retainer amount for a Member of the Board of Directors.
** Annual retainer amounts for the Chair of Committees of the Board of Directors are in lieu of the annual retainer amount for a Member of the applicable Committee of the Board of Directors.

Except as otherwise set forth in this Policy, all Annual Fees shall be paid for the period from January 1 through December 31 of each year. Such Annual Fees shall be paid in cash or a grant of an option to purchase Common Stock under the Stock Plan, at the election of each Non-Employee Director, as follows:

- cash in the amount of each Non-Employee Director's Annual Fees; or

- an option to purchase such number of shares of Common Stock as is equal to the full dollar amount of each Non-Employee Director's Annual Fees (as calculated below under "Calculation of Shares and Grant Terms").

Election

Each Non-Employee Director shall make an annual election on the form provided by the Company, indicating the combination of cash and/or Common Stock elected in the year prior to the payment, indicating his or her election for the following calendar year. If no election has been made prior to the first date of the calendar year, then the Non-Employee Director shall receive all Annual Fees in cash. Each newly elected or appointed Non-Employee Director shall make an election prior to the beginning of the next calendar quarter after his or her initial appointment or election.

Payments

Payments payable to Non-Employee Directors shall be paid quarterly in arrears promptly following the end of each calendar quarter, provided that (i) the amount of such payment shall be prorated for any portion of such quarter that such director was not serving on the Board or a committee or, in the case of the Annual Fees paid for service as a chairperson, as a chairperson, and (ii) no fee shall be payable in respect of any period prior to the date such director was elected to the Board or a committee or, in the case of the Annual Fees paid for service as a chairperson, as a chairperson.

Calculation of Shares and Grant Terms

If an option to purchase Common Stock is to be received as payment, the number of shares underlying such option shall equal the Black Scholes value of the options computed in accordance with FASB Topic 718 on the 25th day of the month following the end of each calendar quarter (the "Calculation Date") (rounded down to the nearest whole number so that no fractional shares

shall be issued). The option shall be automatically and without any further action required by the Board of Directors issued as of the Calculation Date and shall be fully vested as of the date of grant.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and committees thereof or in connection with other business related to the Board of Directors.

Amendments

The Compensation Committee shall periodically review this Policy to assess whether any amendments in the type and amount of compensation provided herein should be made and shall make recommendations to the Board of Directors for its approval of any amendments to this Policy.

Addendum No. 1

to the Rental Agreement dated October 16 / 24, 2018

(regarding space in the building Zeppelinstr. 3, 85399 Hallbergmoos)

Hallbergmoos Grundvermögen GmbH

(registered in the commercial registry of the lower court Munich under the no. **HRB** 220581)

Bavariafilmplatz 7, 80231 Grünwald

Represented by the persons indicated by name in the signature line

- hereinafter **„Landlord"** -

and

Pieris Pharmaceuticals GmbH

(registered in the commercial registry of the lower court Munich under the no. HRB 221043)

VAT Identification No: DE 813177203

Lise-Meitner-Str. 30, 85354 Freising

Represented by the persons indicated by name in the signature line

- hereinafter „**Tenant**" -

- Landlord and Tenant collectively hereinafter „**Parties**" -

Preamble:

The Parties have concluded a rental agreement dated October 16 /24, 2018 – hereinafter: "Rental Agreement" – covering office space, laboratory space and technical space and parking spaces in the building Zeppelinstr. 3, 85399 Hallbergmoos (hereinafter: "Building").

The building permit stated in the Rental Agreement as a condition precedent exists. Consequently, the condition has been fulfilled so that the right to rescission in Sec. 1.7 of the Rental Agreement has expired.

Additionally, the Landlord has conducted a new site measuring with respect to the rental spaces. On this basis minor deviations with respect to the rental spaces have arisen which the Parties intend to clarify by this Addendum.

Therefore the Parties agree on the following:

1. Condition Precedent and Rescission

1.1 Fulfilment of Condition Precedent

Making reference to Sec. 1.6 of the Rental Agreement, the Parties note that the competent public authority has issued an immediately executable building permit on March 26, 2019 which had been stated in the Rental Agreement as a condition precedent.

A copy of this building permit is included in **Annex 1.1** to this Addendum. The Landlord has informed the Tenant of the building permit's issuance immediately on the same date.

The Parties therefore note that the condition precedent stated under Sec. 1.6 of the Rental Agreement has been validly fulfilled.

1.2 Expiration of Right of Rescission

Additionally, the Parties note that due to the timely fulfilment of the condition precedent the Parties' mutual right of rescission stated in Section 1.7 of the Rental Agreement has expired and consequently no Party has a right to declare rescission pursuant to Section 1.7 of the Rental agreement.

2. Rental Object

2.1 In preparation for the extension work, the Landlord has had a new site measurement of the rental property drawn up. For this reason, it is necessary to clarify the areas agreed in Section 1.2 of the Rental Agreement:

The Landlord rents to the Tenant for Tenant's sole use the following areas in the building Zeppelinstr. 3 in 85399 Hallbergmoos, which are listed below and are outlined in red in Annex 1.2 and are to be converted in accordance with the provisions of this agreement (in particular Sec. 2)

a) Technical Space in the lower floor with approx. 530,35 m2
b) Office space and laboratory space on the ground floor (MB 11, 12, 13, 14, 16, 17, 18) with approx. 4.273,44 m2
c) Office space and laboratory space on the first floor (MB 11, 12, 13, 14, 18) with approx. 3.438,43 m2
d) Office and storage space in the second floor (MB 17) with approx. 578,06 m2
e) Office space in the third floor (MB11) with approx. 474,14 m2
f) Office space and laboratory space on the ground floor (MB 17a) with approx. 331,74 m^2

2.2 The aforementioned deviation in the property's size from the rental area originally agreed in the Rental Agreement is 1.37%. With reference to Sec. 1.2 of the Rental Agreement, the Parties thus note that the deviation of the rental areas' size has no effect on the rental provisions concluded by the Parties. In deviation of Sec. 1.2 of the Rental Agreement, the Parties however agree that the ancillary costs in the future shall be apportioned to the Tenant on the basis of the area sizes stated in this Addendum.

2.3 Should contrary to expectation there be additional deviations in the actual area's size to those stated approximately above, for measuring the discrepancy in size and the tolerance level stated in the Rental Agreement in the future, the previously agreed size stated in the Rental Agreement shall continue to be the basis.

3. Miscellaneous

3.1 The Parties are aware that the Rental Agreement to which this Addendum refers requires the statutory written form of Sec. 126 German Civil Code ("BGB") due to the fact that its term has a duration of more than one year according to Secs. 550, 578 (2) BGB. The Parties wish to adhere to this written form.

a) They therefore undertake mutually to perform all acts and make all declarations necessary to comply with the statutory written form requirements at the request of either of the Parties at any time.

b) They additionally shall not terminate this contractual relationship prematurely on the grounds of non-compliance with the statutory written form.

c) The rights and obligations stated in lit. a) and lit b) shall apply not only for this Addendum, but also for the original agreement and all future amendments, addenda and other agreements modifying the agreement(s).

3.2 A third party entering into the contract in accordance with Sec. 566 BGB or by way of a tripartite contract shall not be bound by the obligations arising from Sec. 3.1; such third party shall be entitled to the statutory rights without restriction. This shall not apply in so far as the parts of the contract which do not comply with the written form requirement were known or should have been known to the third party prior to its entry into the Rental Agreement, or if the parts not complying with the written form requirement only came into existence after the third party's entry into the Rental Agreement

However, the joining third party shall in any case be entitled without restriction to the rights arising for the third party from Sec. 3.1 vis-à-vis the other contracting party

3.3 The written form shall also apply to any subsidiary or ancillary agreements, amendments and supplements to this contract which are not subject to the statutory written form requirement of Sec. 126 BGB pursuant to Secs. 550, 578 (2) BGB. This written form requirement can only be waived in writing. Such subsidiary or ancillary agreements, amendments and supplements have to be expressly identified as such and signed by representatives of the party expressly authorized. The written form mentioned in sentence 1 shall not be complied with by declarations made by e-mail or in electronic form. The Parties agree that no ancillary agreements have been made.

3.4 Severability

Should any provision of this Addendum be invalid or unenforceable, the validity of the remaining provisions of this Addendum shall remain unaffected. The Parties shall agree on a provision which comes as close as possible to the economically intended one in place of the affected provisions.

4. Survival of Other Rental Agreement's Provisions

Without prejudice to the provisions agreed in this Addendum, the provisions of the Rental Agreement and its annexes, to which reference is hereby made, shall otherwise remain in force.

5. Addendum's Conclusion, Acceptance Period

The Party signing this Addendum first shall be bound by the contractual offer for a duration of eight weeks from receipt of the offer by the other Party. The acceptance period shall be deemed to have been observed if the first signing party receives the countersigned Addendum no later than on the last day of the aforementioned period.

Signature page:

For the Landlord:

Place, Date: 21/05/2019

Signature: /s/ David Christmann

Name: David Christmann

Position CEO

For the Tenant:

Place, Date: Freising, 29/04/2019

Signature: /s/ Stephen Yoder

Name: Stephen Yoder

Position: Managing Director

Place, Date: Freising, 29/04/2019

Signature: /s/ Allan Reine

Name: Allan Reine

Position Managing Director

Addendum No. 2

to the Rental Agreement dated October 16 / 24, 2018 and

Addendum No. 1 dated May 21- 2019

(regarding space in the building Zeppelinstr. 3, 85399 Hallbergmoos)

Hallbergmoos Grundvermögen GmbH

(registered in the commercial registry of the lower court Munich under the no. **HRB** 220581)

Bavariafilmplatz 7, 80231 Grünwald

Represented by the persons indicated by name in the signature line

- hereinafter **„Landlord"** -

and

Pieris Pharmaceuticals GmbH

(registered in the commercial registry of the lower court Munich under the no. HRB 221043)

VAT Identification No: DE 813177203

Lise-Meitner-Str. 30, 85354 Freising

Represented by the persons indicated by name in the signature line

- hereinafter „**Tenant**" -

- Landlord and Tenant collectively hereinafter „**Parties**" -

Preamble:

The Parties have concluded a rental agreement dated October 16 /24, 2018 – hereinafter: "Rental Agreement" – covering office space, laboratory space and technical space and parking spaces in the building Zeppelinstr. 3, 85399 Hallbergmoos (hereinafter: "Building").

Within the scope of the extension of the rental space by the Landlord, the Tenant has commissioned special requests, which are subject to a charge and which deviate from the previous construction schedule. In addition, an expansion of the rental space is necessary due to the current planning. Furthermore, the contractually agreed handover date could not be met due to construction delays. The Parties wish to clarify the resulting changes compared to the Rental Agreement plus Addendum no. 1 with this Addendum.

Therefore the Parties agree on the following:

1. Rental Space and Handover

1.1 In addition to the existing rented space, the Landlord shall rent to the Tenant the cellar room U.17 with a size of approx. 84.02 m² as marked in Annex 1.1 to this Addendum for the installation of the redundant refrigeration technology. Room U.27 with a size of approx. 93.65 m² is no longer part of the rented space. All areas in the basement within the meaning of Sec. 1.2.a) of this Addendum are outlined in red in **Annex 1.1** of this Addendum.

1.2 The rental space in the object Zeppelinstr. 3 in 85399 Hallbergmoos consequently consists of the following:

a) Technical Space in the lower floor with approx. 520,72 m²
b) Office space and laboratory space on the ground floor (MB 11, 12, 13, 14, 16, 17, 18) with approx. 4.273,44 m²
c) Office space and laboratory space on the first floor (MB 11, 12, 13, 14, 18) with approx. 3.438,43 m²
d) Office and storage space in the second floor (MB 17) with approx. 579,04 m²
e) Office space in the third floor (MB11) with approx. 474,14 m²
f) Office space and laboratory space on the ground floor (MB 17a) with approx. 331,74 m²

1.3 All other agreements regarding the rented areas, in particular in section 2 of Addendum No. 1, shall remain in full effect and shall apply to the rental of the basement area U.17 accordingly.

1.4 Sec. 2.11.4 of the Rental Agreement shall be modified so that the latest date for handing over the rented areas according to Sec. 1, no. 1.2 lit. a), b), c)., d) and f) shall be February 13, 2020 and the latest date for handing over the rented areas according to Sec. 1 no. 1.2 lit. e) shall be May 1, 2020.

For the sake of clarification, the Parties note that the rental term for all areas rented shall start February 13, 2020 and ends with the end of August 13, 2032 pursuant to Sec. 4.1 of the Rental Agreement.

With regard to the amendment of the above newly regulated latest handover dates, the Parties expressly state that this does not imply any waiver of rights which may result from a later handover or its announcement (in comparison to the original rental agreement regulations).

1.5 With regard to room U.27 in the basement, the Parties have agreed that the Tenant will rent this as a further "extension area" pursuant to Sec. 1.4 a.). **Annex 1.2** to this Addendum No. 2 shows the extension areas with green borders and the option areas pursuant to Sec. 1.4 b.) with orange borders and replaces Annex 1.4 to the Rental Agreement.

2. Rent

2.1 Taking into account the rental of the space specified in Sec.1 of this Addendum, the Parties clarify the Tenant's obligation to pay the rent as follows:

2.2 The monthly rent, in each time from handing over the respective areas specified below on shall be:

Technical Space in the lower floor		3.384,68 €
Office space and laboratory space on the ground floor (MB 11,12, 13, 14, 16, 17,18)		70.298,35 €
Office space and laboratory space on the first floor (MB 11, 12, 13, 14, 18)		54.842,96 €
Office and storage space in the second floor (MB 17)		9.220,06 €
Office space in the third floor (MB 11)		7.562,53 €
Office space and laboratory space on the ground floor (MB 17a)		5.291,25 €
Parking spaces in the basement, 100 pieces		7.500,00 €
„**monthly basic rent**“		**158.099,83 €**
advance heating and service charge payments	3,00 €/m²	28.849,59 €
Administrative lump-sum 4 %		6.323,99 €

Monthly total net amount	**193.273,41 €**
Plus statutory VAT (presently 19%)	36.721,95 €
Monthly total gross amount	**229.995,36 €**

2.3 All other agreements between the Parties regarding the rent shall remain fully effective and shall apply accordingly to this Addendum, in particular the provision regarding the "rent-free period" in Sec. 5.1 of the Rental Agreement.

3. Special Tenant's Requests

3.1 In accordance with Sec. 2.10 of the Rental Agreement, the Tenant has commissioned special requests from the Landlord which are associated with additional costs. The following special requests shall be carried out by the Landlord. The Tenant shall bear the costs arising from these requests in the amount specified below.

3.2 Specification of Tenant's Requests

Special Tenant's Request	No. Decision Memorandum	Net-Costs to be borne by Tenant	Annex to Addendum
Adaptation planning floor plans and expansion to tenants' wishes	1	28.750,00 €	3.2.1
vestibule and glass canopy	2b	25.965,15 €	3.2.2
Glass walls and windows	2b	97.427,88 €	3.2.3
Mobile partitions	2b	53.581,31 €	3.2.4
Drywall construction doors	2b	11.735,63 €	3.2.5
Drywall construction ceiling	2c	26.827,21 €	3.2.6
Flooring	3	45.405,36 €	3.2.7
Technical building equipment	4	86.362,10 €	3.2.8
Railing roof	5	19.612,13	3.2.9
Expansion basement	6	19.049,89	3.2.10
Technical building equipment – cold	9	28.027,55	3.2.11
Technical building equipment – special lightning including dimmer and cabling	11	46.201,99	3.2.12

Total net amount		488.946,20 €	
Plus statutory applicable VAT		92.899,78 €	
Total gross amount		**581.845,98 €**	

The Tenant shall pay the total amount of the costs of the Tenant's special requests determined above to the Landlord in accordance with Sec. 2.10 within 30 days after proper invoicing.

3.3 With regard to the details of the changes to the building description and planning associated with the Tenant's special requests, reference is made in each case to the decision papers, including their appendices, attached in **Volume-Annex 3**.

3.4 The Parties agree that the Tenant shall maintain, service and repair the additional equipment of the rental object installed in accordance with the Tenant's special requests, i.e. the vestibule, the glass canopy, the glass walls and windows, the mobile partitions and doors, in accordance with Sec. 7.3 of the Rental Agreement. All operating costs resulting therefrom shall be borne by the Tenant.

4. Supplement to Sec. 7.7.2 of the Rental Agreement

4.1 Due to mandatory technical necessities, there are lines of the adjacent tenant of the rented area 17 in the area rented here on 1st floor MB 18. Similarly, there are technical lines for the rented area of the Tenant in the adjacent area MB 17. In addition to the provisions under Sec. 7.2.2, however under the obligation to adhere to the obligations stated therein, the Landlord may enter the rented area in the 1st floor MB 18, provided that this is necessary for the maintenance, servicing or repair of this line and in particular of the fire protection flaps located there. The Landlord shall ensure that the Tenant is given access to the rented space 17 for maintenance work concerning Tenant’s technical lines in the rented space 17 under the same conditions.

4.2 In this respect, the Parties expressly state that the business operations of the Tenant may not be significantly impaired by this work to the extent possible. The Landlord shall take into account Tenant’s operational concerns. Necessary expenses incurred by the Tenant as a result of tolerating the aforementioned measures shall be borne by the Landlord. The necessary measures shall be announced with an appropriate period of notice.

5. Miscellaneous

5.1 The Parties are aware that the Rental Agreement to which this Addendum refers requires the statutory written form of Sec. 126 German Civil Code (“BGB”) due to the fact that its term has a duration of more than one year according to Secs. 550, 578 (2) BGB. The Parties wish to adhere to this written form.

a) They therefore undertake mutually to perform all acts and make all declarations necessary to comply with the statutory written form requirements at the request of either of the Parties at any time.

b) They additionally shall not terminate this contractual relationship prematurely on the grounds of non-compliance with the statutory written form.

c) The rights and obligations stated in lit. a) and lit. b) shall apply not only for this Addendum, but also for the original agreement and all future amendments, addenda and other agreements modifying the agreement(s).

5.2 A third party entering into the contract in accordance with Sec. 566 BGB or by way of a tripartite contract shall not be bound by the obligations arising from Sec. 3.1; such third party shall be entitled to the statutory rights without restriction. This shall not apply in so far as the parts of the contract which do not comply with the written form requirement were known or should have been known to the third party prior to its entry into the Rental Agreement, or if the parts not complying with the written form requirement only came into existence after the third party's entry into the Rental Agreement.

However, the joining third party shall in any case be entitled without restriction to the rights arising for the third party from Sec. 3.1 vis-à-vis the other contracting party.

5.3 The written form shall also apply to any subsidiary or ancillary agreements, amendments and supplements to this contract which are not subject to the statutory written form requirement of Sec. 126 BGB pursuant to Secs. 550, 578 (2) BGB. This written form requirement can only be waived in writing. Such subsidiary or ancillary agreements, amendments and supplements have to be expressly identified as such and signed by representatives of the party expressly authorized. The written form mentioned in sentence 1 shall not be complied with by declarations made by e-mail or in electronic form. The Parties agree that no ancillary agreements have been made.

5.4 Severability

Should any provision of this Addendum be invalid or unenforceable, the validity of the remaining provisions of this Addendum shall remain unaffected. The Parties shall agree on a provision which comes as close as possible to the economically intended one in place of the affected provisions.

6. Survival of Other Rental Agreement's Provisions

Without prejudice to the provisions agreed in this Addendum, the provisions of the Rental Agreement including its First Amendment and its annexes, to which reference is hereby made, shall otherwise remain in force.

7. Addendum's Conclusion, Acceptance Period

The Party signing this Addendum first shall be bound by the contractual offer for a duration of eight weeks from receipt of the offer by the other Party. The acceptance period shall be deemed to have been observed if the first signing party receives the countersigned Addendum no later than on the last day of the aforementioned period.

Annex 1.1	Floor Plans
Annex 1.2	Expansion and option area
Annex 3.2.1	Adaptation planning floor plans and expansion to tenants' wishes
Annex 3.2.2	Vestibule and glass canopy
Annex 3.2.3	Glass walls and windows
Annex 3.2.4	Mobile partitions
Annex 3.2.5	Drywall construction doors
Annex 3.2.6	Drywall construction ceiling
Annex 3.2.7	Flooring
Annex 3.2.8	TGA
Annex 3.2.9	Railing roof
Annex 3.2.10	Expansion basement
Annex 3.2.11	TGA – cold
Annex 3.2.12	TGA – special lightning including dimmer and cabling

For the Landlord:

Place, Date: Grünwald, the 12.02.2019

Signature: /s/ Christian Lealahabumrung

Name: Christian Lealahabumrung

Position CEO

For the Tenant:

Place, Date: Freising, 13.02.2020

Signature: /s/ Hitto Kaufmann

Name: Dr. Hitto Kaufmann

Position: Managing Director

Exhibit 14.1

PIERIS PHARMACEUTICALS, INC.
CORPORATE CODE OF CONDUCT AND ETHICS
AND
WHISTLEBLOWER POLICY

(EFFECTIVE DATE: APRIL 30, 2019)

INTRODUCTION

This Corporate Code of Conduct and Ethics and Whistleblower Policy, referred to as the "Code," is intended to provide our associates, as defined below, with a clear understanding of the principles of business conduct and ethics that are expected of them and to aid them in making ethical and legal decisions when conducting the company's business and performing day-to-day duties. The standards set forth in the Code apply to us all. Every associate of the company must acknowledge his or her review of, and agreement to comply with, the Code as a condition of his or her relationship with the company (see Appendix A attached hereto). The terms "us" or "associate" as used throughout the Code means (i) every full and part-time employee of the company and its subsidiaries, (ii) all members of the company's senior management, including the company's Chief Executive Officer and Chief Financial Officer, and (iii) every member of the company's Board of Directors, even if such member is not employed by the company. The term "you" means any associate.

REPORTING VIOLATIONS UNDER THE CODE; ANTI-RETALIATION PLEDGE

It is our responsibility to conduct ourselves in an ethical business manner and to ensure that others do the same. If any one of us violates these standards, he or she can expect a disciplinary response, up to and including termination of any employment or other relationship with the company, and possibly other legal action. If you are aware of any breach of the Code, you are obligated to report violations to the Corporate Compliance Officer, to any member of the Compliance Committee, or to the anonymous Whistleblower Compliance Hotline (the "Hotline") that the company has retained to receive such reports and forward them directly to the Audit Committee, as described in more detail below. Through establishing a confidential and anonymous option to accept and process such reports, we ensure that the good faith efforts of all of us to comply with the Code are not undermined.

The Code contains a clear anti-retaliation pledge, meaning that if you in good faith report a violation of the Code by the company, or its agents acting on behalf of the company, to the Hotline, the Corporate Compliance Officer or another member of the Compliance Committee, the company will undertake to protect you from being fired, demoted, reprimanded or otherwise harmed for reporting the violation, even if the violation involves you, your supervisor, or senior management of the company. Note, however, that while you will not be disciplined for reporting a violation, you may be subject to discipline with respect to the underlying conduct or violation. You are entitled to make the report on a confidential and anonymous basis. To the extent an investigation must be initiated, the company will keep confidential any report you make to the Corporate Compliance Officer or another member of the Compliance Committee to the extent required by applicable law.

COMPLYING WITH THE CODE

The ultimate responsibility for maintaining our Code rests with each of us. As individuals of personal integrity, we can do no less than to behave in a way that will continue to bring credit to ourselves and our company. Applying these standards to our business lives is an extension of the values by which we are known as individuals and by which we want to be known as a company. To that end, the company has made the Code publicly available on its website. It is our responsibility to conduct ourselves in an ethical business manner and to ensure that others do the same. If any one of us violates these standards, he or she can expect a disciplinary response, up to and including termination of any employment or other relationship with the company, and possibly other legal action.

While it is impossible for this Code to describe every situation that may arise, the standards explained in this Code are guidelines that should govern our conduct at all times. If you are confronted with situations not covered by this Code or have questions regarding the matters that are addressed in the Code, you are urged to consult with the Corporate Compliance Officer, a member of the Compliance Committee, or another member of management. Furthermore, the policies set forth in this Code are in addition to other policies of the company that associates must comply with. Copies of these other policies are available from the Human Resources Department or on the company's Intranet.

The provisions of the Code regarding the actions the company will take are guidelines which the company intends to follow. There may be circumstances, however, that in the company's judgment require different measures or actions and, in such cases, it may act accordingly while still attempting to fulfill the principles underlying this Code. In the case of any inconsistency between the provisions set out in this Code and the rules contained in any mandatory text, laws or interpretive case law applicable to the company and its associates, the latter prevail. In no instance should this Code be interpreted as modifying, amending or otherwise changing any legal text and related legal precedents that apply to the company and its associates.

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APPENDIX A

ASSOCIATE'S AGREEMENT TO COMPLY A-1

I. WHISTLEBLOWER POLICY

A. Obligation to Report Violations or Suspected Violations

Any associate of the company having any information or knowledge regarding the existence of any violation or suspected violation of the Code has a duty to report the violation or suspected violation to the Hotline (the contact details for which are below), the Corporate Compliance Officer, or any other member of the Compliance Committee. Associates are also encouraged to raise any issues or concerns regarding the company's business or operations. Failure to report suspected or actual violations is itself a violation of the Code and may subject the associate to disciplinary action, up to and including termination of employment or legal action. Reports may be made on a completely confidential and anonymous basis. To the extent any investigation is necessitated by a report, the company will endeavor to keep the proceedings and the identity of the reporting associate confidential to the fullest extent required by applicable law.

Associates are encouraged to pursue all internal reporting channels through completion and reasonably await and consider the results of all internal investigations prior to reporting matters outside of the company. We have instituted the procedures described in this Code, including procedures to make anonymous submissions (a form of internal report), to facilitate the use of internal investigations.

Individuals should also consider leaving, but are not required to leave, their name or a contact number when submitting a report. Such information may facilitate a more thorough and efficient investigation. The Corporate Compliance Officer will strive to maintain the integrity and confidentiality of all compliance-related communications. However, in certain circumstances, the identity of the person reporting the issue may become known or may need to be revealed, particularly if federal or state enforcement authorities become involved in the investigation. The company cannot guarantee confidentiality when material evidence of a violation of the law is disclosed or if the person is identified during the normal course of an investigation.

B. Whistleblower Compliance Hotline for Confidential and Anonymous Reporting

If you are aware of any breach of the Code, you are obligated to report violations to the Corporate Compliance Officer, to any member of the Compliance Committee, or to the Hotline. The Hotline is operated by a third-party service provider, which the company has engaged to receive such reports, the contact details for which are below. **You may make such reports on an anonymous and confidential basis by submitting a report to or calling the Hotline.** Associates may report to the Hotline any concerns an associate may have with respect to the company, including, but not limited to, concerns with the company's business or operations, suspected violations of the Code, securities or antifraud laws, accounting issues, any law relating to fraud against shareholders, or any other issue concerning the company and their employment with the company. Reports made to the Hotline will, in turn, be provided directly to the Audit Committee on an anonymous and confidential basis. The Hotline may be reached 24 hours a day, 7 days a week as follows:

Primary Website: www.lighthouse-services.com/pieris

Toll-Free Telephone Number (U.S. & Canada): 1-833-740-0003

Telephone Number (All Other Countries): 1-800-603-2869

C. Anti-Retaliation Pledge

Any associate who in good faith reports a suspected violation under the Code by the company, or its agents acting on behalf of the company, or who in good faith raises issues or concerns regarding the company's business or operations, to the Hotline, the Corporate Compliance Officer or any other member of the Compliance Committee, may not be fired, demoted, reprimanded or otherwise harmed for, or because of, the reporting of the suspected violation, issues or concerns, regardless of whether the suspected violation involves the associate, the associate's supervisor or senior management of the company.

In addition, any associate who in good faith reports a suspected violation under the Code which the associate reasonably believes constitutes a violation of a federal statute by the company, or its agents acting on behalf of the company, to a federal regulatory or law enforcement agency, may not be reprimanded, discharged, demoted, suspended, threatened, harassed or in any manner discriminated against in the terms and conditions of the associate's employment for, or because of, the reporting of the suspected violation, regardless of whether the suspected violation involves the associate, the associate's supervisor or senior management of the company.

II. IMPLEMENTATION OF THE CODE

The following questions and answers address the company's implementation of the Code. The company has attempted to design procedures that ensure maximum confidentiality, anonymity, and, most importantly, freedom from the fear of retaliation for complying with and reporting violations under the Code. In addition, each associate shall sign the Associate's Agreement to Comply with the Code in substantially the form attached as Appendix A hereto.

Q: Who is responsible for administering, updating and enforcing the Code?

A: The company's Board of Directors has appointed a Corporate Compliance Officer and a Compliance Committee that includes the Corporate Compliance Officer and at least one additional member to administer, update and enforce the Code. Ultimately, the Board of Directors of the company must ensure that the Corporate Compliance Officer and the Compliance Committee fulfill their responsibilities.

The Corporate Compliance Officer has overall responsibility for overseeing the implementation of the Code. Specific responsibilities of the position are to:

- Develop the Code based on legal requirements, regulations and ethical considerations that are raised in the company's operations;

- Ensure that the Code is distributed to all associates and that all associates acknowledge the principles of the Code;

- Work with the company's Audit Committee to provide a reporting mechanism so that associates have a confidential and anonymous method of reporting not only suspected violations of the Code but concerns regarding federal securities or antifraud laws, accounting issues, or any federal law relating to fraud against shareholders;

- Implement a training program to ensure that associates are aware of and understand the Code;

- Audit and assess compliance with the Code;

- Serve as a point person for reporting violations and asking questions under the Code; and

- Revise and update the Code as necessary to respond to detected violations and changes in the law.

The Compliance Committee is comprised of the Corporate Compliance Officer, and at least one additional member selected from a representative from the Human Resources Department, a representative from the Finance Department, a representative from the Legal Department and/or a member of the executive management team. The primary responsibilities of the Compliance Committee are to:

- Assist the Corporate Compliance Officer in developing and updating the Code;

- Develop internal procedures to monitor and audit compliance with the Code;

- Serve as point persons for reporting violations and asking questions under the Code;

- Set up a mechanism for anonymous reporting of suspected violations of the Code by associates and refer, when appropriate, such reports to the Audit Committee;

- Conduct internal investigations, with the assistance of counsel, of suspected compliance violations;

- Evaluate disciplinary action for associates who violate the Code;

- In the case of more severe violations of the Code, make recommendations regarding disciplinary action to the Board of Directors or a committee thereof; and

- Evaluate the effectiveness of the Code and improve the Code.

The Compliance Committee will provide a summary of all matters considered under the Code to the Board of Directors or a committee thereof at each regular meeting thereof, or sooner

if warranted by the severity of the matter. All proceedings and the identity of the person reporting will be kept confidential to the extent required by applicable law.

Q: How can I contact the Corporate Compliance Officer and the Compliance Committee?

A: The names, email addresses and phone numbers of the Corporate Compliance Officer and each member of the Compliance Committee are listed below. Any one of these individuals can assist you in answering questions or reporting violations or suspected violations under the Code.

Ahmed Mousa, General Counsel Corporate Compliance Officer	**+1-857-250-0363** **mousa@pieris.com**
Tom Bures, VP Finance Compliance Committee Member	**+1-857-957-3581** **bures@pieris.com**

The members of the Compliance Committee may change from time to time. You are encouraged to consult the copy of the Code that is included on the company's website to obtain the most current membership of the Compliance Committee.

III. GENERAL REQUIREMENTS

Each associate of the company is expected to be honest, fair, and accountable in all business dealings and obligations, and to ensure:

- the ethical handling of conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in the reports required to be filed by the company with the Securities and Exchange Commission and in other public communications made by the company; and
- compliance with applicable governmental laws, rules and regulations.

IV. CONFLICTS OF INTEREST

Associates should avoid any situation that may involve, or even appear to involve, a conflict between their personal interests and the interests of the company. In dealings with current or potential customers, suppliers, contractors, and competitors, each associate should act in the best interests of the company to the exclusion of personal advantage Immediate family members of associates, executive officers and directors are also covered in certain circumstances. For purposes of this section, a "significant" amount or interest shall be deemed to be any amount in excess of $120,000 and an "immediate family member" in respect of any person means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of such person, and any person (other than a tenant or employee) sharing the household of such person.

Associates and, in certain circumstances, their immediate family members, are prohibited from any of the following activities which could represent an actual or perceived conflict of interest:

- No associate or immediate family member of an associate shall have a significant financial interest in, or obligation to, any outside enterprise which does or seeks to do business with the company or which is an actual or potential competitor of the company, without prior approval of the Compliance Committee, or in the case of executive officers or members of the Board of Directors, the full Board of Directors or a committee thereof; provided however, that this provision shall not prevent any associate from investing in any mutual fund or owning up to 1% of the outstanding stock of any publicly traded company.

- No associate shall conduct a significant amount of business on the company's behalf with an outside enterprise which does or seeks to do business with the company if an immediate family member of the associate is a principal or officer of such enterprise, or an employee of such enterprise who will play a significant role in the business done or to be done between the company and such enterprise, without prior approval of the Compliance Committee, or in the case of executive officers or members of the Board of Directors, the full Board of Directors or a committee thereof.

- No executive officer or employee, or an immediate family member of an executive officer or an employee, shall serve as a director, officer or in any other management or consulting capacity of any actual competitor of the company.

- No director, or an immediate family member of a director, shall serve as a director, officer or in any other management or consulting capacity of any actual competitor of the company, without the prior approval of the full Board of Directors or a committee thereof.

- No associate shall use any company property or information or his or her position at the company for his or her personal gain.

- No associate shall engage in activities that are directly competitive with those in which the company is engaged.

- No associate shall divert a business opportunity from the company to such individual's own benefit. If an associate becomes aware of an opportunity to acquire or profit from a business opportunity or investment in which the company is or may become involved or in which the company may have an existing interest, the associate should disclose the relevant facts to the Corporate Compliance Officer or a member of the Compliance Committee. The associate may proceed to take advantage of such opportunity only if the company is unwilling or unable to take advantage of such opportunity as notified in writing by the Compliance Committee.

- No associate or immediate family member of an associate shall receive any loan or advance from the company or be the beneficiary of a guarantee by the company of a loan or advance from a third party, except for customary advances or corporate credit in the ordinary course of business or approved by the Compliance Committee. Please see Section V.E. below, "Corporate Advances", for more information on permitted corporate advances.

In addition, the Audit Committee of the Board of Directors will review and approve, in advance, all "Related-Person Transactions" (as defined under Item 404 of Regulation S-K promulgated under the Securities Act of 1933, as amended), as required by the Securities and Exchange Commission, The Nasdaq Stock Market or any other regulatory body to which the company is subject.

Each associate should make prompt and full disclosure in writing to the Corporate Compliance Officer or a member of the Compliance Committee of any situation that may involve a conflict of interest. Failure to disclose any actual or perceived conflict of interest is a violation of the Code.

V. PROTECTION AND PROPER USE OF COMPANY ASSETS

Proper protection and use of company assets and assets entrusted to it by others, including proprietary information, is a fundamental responsibility of each associate of the company. Associates must comply with security programs to safeguard such assets against unauthorized use or removal, as well as against loss by criminal act or breach of trust. The provisions hereof relating to protection of the company's property also apply to property of others entrusted to it (including proprietary and confidential information).

A. Proper Use of Company Property

The removal from the company's facilities of the company's property is prohibited, unless authorized by the company. This applies to furnishings, equipment, and supplies, as well as property created or obtained by the company for its exclusive use — such as client lists, files, personnel information, reference materials and reports, computer software, data processing programs and data bases. Neither originals nor copies of these materials may be removed from the company's premises or used for purposes other than the company's business without prior written authorization from the Compliance Committee.

The company's products and services are its property; contributions made by any associate to their development and implementation are the company's property and remain the company's property even if the individual's employment or directorship terminates.

Each associate has an obligation to use the time for which he or she receives compensation from the company productively. Work hours should be devoted to activities directly related to the company's business.

B. Confidential Information

The company provides its associates with confidential information relating to the company and its business with the understanding that such information is to be held in confidence and not communicated to anyone who is not authorized to see it, except as may be required by law. The types of information that each associate must safeguard include (but are not limited to) the company's plans and business strategy, unannounced products and/or contracts, sales data, significant projects, customer and supplier lists, patents, patent applications, trade secrets, manufacturing techniques and sensitive financial information, whether in electronic or paper format. These are costly, valuable resources developed for the exclusive benefit of the company. No associate shall disclose the company's confidential information to an unauthorized third party or use the company's confidential information for his or her own personal benefit.

C. Accurate Records and Reporting

Under law, the company is required to keep books, records and accounts that accurately and fairly reflect all transactions, dispositions of assets and other events that are the subject of specific regulatory record keeping requirements, including generally accepted accounting principles and other applicable rules, regulations and criteria for preparing financial statements and for preparing periodic reports filed with the Securities and Exchange Commission. All company reports, accounting records, sales reports, expense accounts, invoices, purchase orders, and other documents must accurately and clearly represent the relevant facts and the true nature of transactions. Reports and other documents should state all material facts of a transaction and not omit any information that would be relevant in interpreting such report or document. Under no circumstance may there be any unrecorded liability or fund of the company, regardless of the purposes for which the liability or fund may have been intended, or any improper or inaccurate entry knowingly made on the books or records of the company. No payment on behalf of the company may be approved or made with the intention, understanding or awareness that any part of the payment is to be used for any purpose other than that described by the documentation supporting the payment. In addition, intentional accounting misclassifications (e.g., expense versus capital) and improper acceleration or deferral of expenses or revenues are unacceptable reporting practices that are expressly prohibited.

The company has developed and maintains a system of internal controls to provide reasonable assurance that transactions are executed in accordance with management's authorization, are properly recorded and posted, and are in compliance with regulatory requirements. The system of internal controls within the company includes written policies and procedures, budgetary controls, supervisory review and monitoring, and various other checks and balances, and safeguards, such as password protection to access certain computer systems.

The company has also developed and maintains a set of disclosure controls and procedures to ensure that all information required to be disclosed by the company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission's rules and forms.

Associates are expected to be familiar with, and to adhere strictly to, these internal controls and disclosure controls and procedures.

Responsibility for compliance with these internal controls and disclosure controls and procedures rests not solely with the company's accounting personnel, but with all associates involved in approving transactions, supplying documentation for transactions, and recording, processing, summarizing and reporting of transactions and other information required by periodic reports filed with the Securities and Exchange Commission. **Because the integrity of the company's external reports to shareholders and the Securities and Exchange Commission depends on the integrity of the company's internal reports and record keeping, all associates must adhere to the highest standards of care with respect to our internal records and reporting. The company is committed to full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by it with the Securities and Exchange Commission, and it expects each associate to work diligently towards that goal.**

Any associate who believes the company's books and records are not in accord with these requirements should immediately report the matter to the Hotline, the Corporate Compliance Officer or a member of the Compliance Committee. The company has adopted explicit anti-retaliation policies with respect to these matters, as described in Section I above.

D. Document Retention

Numerous federal and state statutes require the proper retention of many categories of records and documents that are commonly maintained by companies. In consideration of those legal requirements and the company's business needs, all associates must maintain records in accordance with these laws and, if any, the company's document retention policy.

Any record, in paper or electronic format, relevant to a threatened, anticipated or actual internal or external inquiry, investigation, matter or lawsuit may not be discarded, concealed, falsified, altered, or otherwise made unavailable, once an associate has become aware of the existence of such threatened, anticipated or actual internal or external inquiry, investigation, matter or lawsuit.

When in doubt regarding retention of any record, an associate must not discard or alter the record in question and should seek guidance from the Corporate Compliance Officer or a member of the Compliance Committee. Associates should also direct all questions regarding document retention and related procedures to the Corporate Compliance Officer or a member of the Compliance Committee.

E. Corporate Advances

Under law, the company may not loan money to associates except in limited circumstances. It shall be a violation of the Code for any associate to advance company funds to any other associate or to himself or herself except for usual and customary business advances for legitimate corporate purposes which are approved by a supervisor or pursuant to a corporate credit card for usual and customary, legitimate business purposes. It is the company's policy that any advance to an associate not meeting the forgoing criteria be approved in advance by the Compliance Committee.

Company credit cards are to be used only for authorized, legitimate business purposes. An associate will be responsible for any unauthorized charges to a company credit card.

VI. FAIR DEALING WITH CUSTOMERS, SUPPLIERS, COMPETITORS, AND ASSOCIATES

The company does not seek to gain any advantage through the improper use of favors or other inducements. Good judgment and moderation must be exercised to avoid misinterpretation and adverse effect on the reputation of the company or its associates. Offering, giving, soliciting or receiving any form of bribe to or from an employee of a customer, a supplier, a vendor, service provider, regulatory official, physician, clinical investigator, investigative site or the like to influence its conduct is strictly prohibited.

A. Giving Gifts

Cash or cash-equivalent gifts must not be given by an associate to any person or enterprise. Gifts, favors and entertainment may be given to non-governmental employees if what is given:

- is consistent with customary business practice;
- is not excessive in value and cannot be construed as a bribe or pay-off;
- is not in violation of applicable law or ethical standards; and
- will not embarrass the company or the associate if publicly disclosed.

B. Receiving Gifts

Gifts, favors, entertainment or other inducements may not be accepted by associates or members of their immediate families from any person or organization that does or seeks to do business with, or is a competitor of, the company, except as common courtesies usually associated with customary business practices. If the gift is of more than token value, the Compliance Committee must approve its acceptance.

An especially strict standard applies when suppliers, physicians, clinical investigators or investigative sites are involved. If a gift unduly influences or makes an associate feel obligated to "pay back" the other party with business, receipt of the gift is unacceptable.

It is never acceptable to accept a gift in cash or cash equivalent. Even cash gifts of token value must be declined and returned to the sender.

C. Unfair Competition

Although the free enterprise system is based upon competition, rules have been imposed stating what can and what cannot be done in a competitive environment. The following practices can lead to liability for "unfair competition" and should be avoided. They are violations of the Code.

Disparagement of Competitors. It is not illegal to point out weaknesses in a competitor's service, product or operation; however, associates may not spread false rumors about competitors or make misrepresentations about their businesses. For example, an associate may not pass on anecdotal or unverified stories about a competitor's products or services as the absolute truth (e.g., the statement that "our competitors' diagnostic testing procedures have poor quality control").

Disrupting a Competitor's Business. This includes bribing a competitor's employees, posing as prospective customers or using deceptive practices such as enticing away employees in order to obtain secrets or destroy a competitor's organization. For example, it is not a valid form of "market research" to visit a competitor's place of business posing as a customer.

Misrepresentations of Price and Product. Lies or misrepresentations about the nature, quality or character of the company's services and products are both illegal and contrary to company policy. An associate may only describe our services and products based on their documented specifications, not based on anecdote or his or her belief that our specifications are too conservative.

D. Antitrust Concerns

Federal and state antitrust laws are intended to preserve the free enterprise system by ensuring that competition is the primary regulator of the economy. Every corporate decision that involves customers, competitors, and business planning with respect to output, sales and pricing raises antitrust issues. Compliance with the antitrust laws is in the public interest, in the interest of the business community at large, and in our company's interest.

Failing to recognize antitrust risk is costly. Antitrust litigation can be very expensive and time-consuming. Moreover, violations of the antitrust laws can, among other things, subject you and the company to the imposition of injunctions, treble damages, and heavy fines. Criminal penalties may also be imposed, and individual associates can receive heavy fines or even be imprisoned. For this reason, antitrust compliance should be taken seriously at all levels within the company.

A primary focus of antitrust laws is on dealings between competitors. In all interactions with actual or potential competitors all associates must follow these rules:

- Never agree with a competitor or a group of competitors to charge the same prices or to use the same pricing methods, to allocate services, customers, private or governmental payor contracts or territories among yourselves, to boycott or refuse to do business with a provider, vendor, payor or any other third party, or to refrain from the sale or marketing of, or limit the supply of, particular products or services.

- Never discuss past, present, or future prices, pricing policies, bundling, discounts or allowances, royalties, terms or conditions of sale, costs, choice of customers, territorial markets, production quotas, allocation of customers or territories, or bidding on a job with a competitor.

- Be careful of your conduct. An "agreement" that violates the antitrust laws may be not only a written or oral agreement, but also a "gentlemen's agreement" or a tacit understanding. Such an "agreement" need not be in writing. It can be inferred from conduct, discussions or communications of any sort with a representative of a competitor.

- Make every output and sales-related decision (pricing, volume, etc.) independently, in light of costs and market conditions and competitive prices.

- Carefully monitor trade association activity. These forums frequently create an opportunity for competitors to engage in antitrust violations.

Another focus of antitrust law is how a company deals with customers, suppliers, contractors and other third parties. The following practices could raise issues, and associates should always consult with the Corporate Compliance Officer or the Compliance Committee before doing any of the following:

- Refusing to sell to any customers or prospective customer;

- Entering into any new distribution or supply agreement which differs in any respect from those previously approved;

- Conditioning a sale on the customer's purchasing another product or service, or on not purchasing the product of a competitor;

- Agreeing with a customer on a minimum or maximum resale price of our products;

- Imposing restrictions on the geographic area to which our customers may resell our products;

- Requiring a supplier to purchase products from the company as a condition of purchasing products from that supplier;

- Entering into an exclusive dealing arrangement with a supplier or customer; or

- Offering different prices, terms, services or allowances to different customers who compete or whose customers compete in the distribution of commodities.

If our company has a dominant or potentially dominant position with respect to a particular product or market, especially rigorous standards of conduct must be followed. In these circumstances, all associates should:

- Consult with the Corporate Compliance Officer or the Compliance Committee before selling at unreasonably low prices or engaging in any bundling practices; and

- Keep the Corporate Compliance Officer or the Compliance Committee fully informed of competitive strategies and conditions in any areas where the company may have a significant market position.

Finally, always immediately inform the Corporate Compliance Officer or the Compliance Committee if local, state or federal law enforcement officials request information from the company concerning its operations.

E. Unfair Practices in International Business

Under the Foreign Corrupt Practices Act ("FCPA"), associates of the company are prohibited from making certain gifts to foreign officials. "Foreign officials" include not only persons acting in an official capacity on behalf of a foreign government, agency, department or instrumentality, but also representatives of international organizations, foreign political parties and candidates for foreign public office. The gift is "corrupt" under the FCPA if it is made for the purpose of:

- Influencing any act or decision of a foreign official in his official capacity;
- Inducing a foreign official to do or omit to do any act in violation of his lawful duty;
- Inducing a foreign official to use his position to affect any decision of the government; or
- Inducing a foreign official to secure any "improper advantage."

A gift is still "corrupt" even when paid through an intermediary. Any associate who has any questions whatsoever as to whether a particular gift might be "corrupt" under the FCPA, please contact the Corporate Compliance Officer or any member of the Compliance Committee.

VII. GOVERNMENT RELATIONS

Associates must adhere to the highest standards of ethical conduct in all relationships with government employees and must not improperly attempt to influence the actions of any public official.

A. Government Procurement and Funding

The U.S. government, governments of other countries and many state, regional and local governments have adopted comprehensive laws and regulations governing the purchase of products from private contractors or the provision of funds to the private sector for research and development. These laws and regulations are intended to assure that governmental entities receive pricing, terms, and/or conditions equivalent to those granted to the company's most favored commercial counterparties and that there is full and open competition in contracting.

When selling products or services to, or seeking funding from, government agencies, the company is accountable for complying with all applicable laws, regulations, and requirements.

Certifications to, and contracts with, government agencies are to be signed by a company associate authorized by the Board of Directors to sign such documents, based upon knowledge that all requirements have been fully satisfied.

B. Payments to Officials

Payments or gifts shall not be made directly or indirectly to any government official or associate if the gift or payment is illegal under the laws of the country having jurisdiction over the transaction, or if it is for the purpose of influencing or inducing the recipient to do, or omit to do, any act in violation of his or her lawful duty. Under no circumstances should gifts be given to any government employees.

C. Political Contributions

Company funds, property or services may not be contributed to any political party or committee, or to any candidate for or holder of any office of any government. This policy does not preclude, where lawful, company expenditures to support or oppose public referendum or separate ballot issues, or, where lawful and when reviewed and approved in advance by the Compliance Committee, the formation and operation of a political action committee.

VIII. COMPLIANCE WITH LAWS, RULES AND REGULATIONS

A. Insider Trading Policy

The company expressly forbids any associate from trading on material non-public information or communicating material non-public information to others in violation of the law. This conduct is frequently referred to as "insider trading." This policy applies to every associate of the company and extends to activities both within and outside their duties to the company, including trading for a personal account.

The concept of who is an "insider" is broad. It includes officers, directors and employees of a company. In addition, a person can be a "temporary insider" if he or she enters into a special confidential relationship in the conduct of a company's affairs and as a result is given access to information solely for the company's purpose. A temporary insider can include, among others, a company's investment advisors, agents, attorneys, accountants and lending institutions, as well as the employees of such organizations. An associate may also become a temporary insider of *another company* with which our company has a contractual or other relationship.

Trading on inside information is not a basis for liability unless the information is material. This is information that a reasonable investor would consider important in making his or her investment decisions, or information that is likely to have a significant effect on the price of a company's securities.

Information is non-public until it has been effectively communicated to the marketplace. Tangible evidence of such dissemination is the best indication that the information is public. For example, information found in a report filed with the Securities and Exchange Commission or appearing in a national newspaper would be considered public.

Each associate should be familiar with and abide by the company's Insider Trading Policy. A copy of this policy is given to all new associates of the company and is available from the Corporate Compliance Officer.

B. Equal Employment Opportunity

The company makes employment-related decisions without regard to a person's race, color, religious creed, age, sex, sexual orientation, marital status, national origin, ancestry, present or past history of mental disorder, mental retardation, learning disability or physical disability, including, but not limited to, blindness and genetic predisposition, or any other factor unrelated to a person's ability to perform the person's job. "Employment decisions" generally mean decisions relating to hiring, recruiting, training, promotions and compensation, but the term may encompass other employment actions as well.

The company encourages its associates to bring any problem, complaint or concern regarding any alleged employment discrimination to the attention of the Corporate Compliance Officer or any member of the Compliance Committee. Associates who have concerns regarding conduct they believe is discriminatory should also feel free to make any such reports to the Corporate Compliance Officer, a member of the Compliance Committee, or the Hotline.

A copy of the company's Equal Employment Opportunity policy is given to all new associates of the company and is available from the Corporate Compliance Officer.

C. Sexual Harassment Policy

The company is committed to maintaining a collegial work environment in which all individuals are treated with respect and dignity and which is free of sexual harassment. In keeping with this commitment, the company will not tolerate sexual harassment of associates by anyone, including any supervisor, co-worker, vendor, client or customer, whether in the workplace, at assignments outside the workplace, at company-sponsored social functions or elsewhere.

Each associate should be familiar with and abide by the company's Sexual Harassment Policy. A copy of this policy is provided to all associates and is available from the Corporate Compliance Officer or any member of the Compliance Committee.

D. Health, Safety & Environment Laws

Health, safety, and environmental responsibilities are fundamental to the company's values. Associates are responsible for ensuring that the company complies with all provisions of the health, safety, and environmental laws of the United States and of other countries where the company does business.

The penalties that can be imposed against the company and its associates for failure to comply with health, safety, and environmental laws can be substantial, and include imprisonment and fines.

E. Health Care Regulations

The company is committed to full compliance with federal and state laws, including laws prohibiting health care fraud and abuse such as the federal and state anti-kickback laws, the physician self-referral law commonly known as the Stark law and the federal and state false claims laws.

The federal anti-kickback statute prohibits the knowing and willful payment of remuneration to a physician, hospital or other source with the intent to induce the physician, hospital or other source to refer patients or order or recommend any items or services paid for by any federal health care program. There are certain "safe harbor" exceptions to this statute; however, their application is complicated. A violation of the federal anti-kickback statute can result in severe penalties, including criminal conviction, fines and exclusion from Medicare and Medicaid programs. Many other jurisdictions, including many states, have similar anti-kickback laws governing items or services payable under government programs or by private insurance companies.

A federal statute similar to the federal anti-kickback statute is the Stark Law. The Stark Law prohibits physicians who have certain financial relationships with health care entities from ordering designated health services for their patients from such entities. Certain safe harbor provisions exist but are complicated in their application. A violation of the Stark Law can result in denial of payment and civil monetary penalties.

Federal and state false claims laws prohibit knowing and willful false statements or representations made in connection with a claim submitted for reimbursement to health care programs such as Medicare and Medicaid. Claims that (i) provide misleading or incomplete information to customers regarding health care products or services, (ii) fail to include proper documentation or show a failure to obtain proper diagnosis information and (iii) bill for services not rendered, coded improperly or otherwise not rendered in the manner required, have resulted in penalties to providers under false claims statues. A violation of a false claims statute can result in severe consequences including civil penalties and criminal conviction.

As the application of federal and state anti-kickback and false claims laws is very complicated and nuanced, it is imperative that an associate with questions about the application of these laws contact the Corporate Compliance Officer a member of the Compliance Committee for guidance in advance of taking any action where any such law may be applicable.

IX. QUESTIONS UNDER THE CODE AND WAIVER PROCEDURES

Associates are encouraged to consult with the Corporate Compliance Officer and Compliance Committee about any uncertainty or questions they may have under the Code.

If any situation should arise where a course of action would likely result in a violation of the Code but for which the associate thinks that a valid reason for the course of action exists, the associate should contact the Corporate Compliance Officer or a member of the Compliance Committee to obtain a waiver **prior to the time the action is taken. No waivers will be granted after the fact for actions already taken.** Except as noted below, the Compliance Committee will review all the facts surrounding the proposed course of action and will determine whether a waiver from any policy in the Code should be granted.

Waiver Procedures for Executive Officers and Directors. Waiver requests by an executive officer or member of the Board of Directors shall be referred by the Compliance Committee, with its recommendation, to the Board of Directors or a committee thereof for consideration. If either (i) a majority of the independent directors on the Board of Directors, or (ii) a committee comprised solely of independent directors agrees that the waiver should be granted, it will be granted. The company will disclose the nature and reasons for the waiver on a Form 8-K to be filed with the Securities and Exchange Commission within four business days or as otherwise permitted by the rules of the Securities and Exchange Commission and The Nasdaq Stock Market. If the Board denies the request for a waiver, the waiver will not be granted and the associate may not pursue the intended course of action.

It is the company's policy only to grant waivers from the Code in limited and extraordinary circumstances.

X. FREQUENTLY ASKED QUESTIONS (FAQ'S) REGARDING REPORTING VIOLATIONS UNDER THE CODE, WHISTLEBLOWER POLICY AND HOTLINE

The following questions and answers address each associate's obligation to comply with the Code. The company has attempted to design procedures that ensure maximum confidentiality and, most importantly, freedom from the fear of retaliation for complying with and reporting violations under the Code.

Q: Do I have a duty to report violations under the Code?

A: Yes, participation in the Code and its compliance program is mandatory. You must immediately report any suspected or actual violation of the Code to the Hotline, the Corporate Compliance Officer or a member of the Compliance Committee. The company will keep reports confidential to the fullest extent required by applicable law. Failure to report suspected or actual violations is itself a violation of the Code and may subject you to disciplinary action, up to and including termination of employment or legal action.

Q: I'm afraid of being fired for raising questions or reporting violations under the Code. Will I be risking my job if I do?

A: The Code contains a clear anti-retaliation pledge, meaning that if you in good faith report a violation of the Code by the company, or its agents acting on behalf of the company, to the Hotline, the Corporate Compliance Officer or another member of the Compliance Committee, the company will undertake to protect you from being fired, demoted, reprimanded or otherwise harmed for reporting the violation, even if the violation involves you, your supervisor, or senior management of the company. Note, however, that while you will not be disciplined for reporting a violation, you may be subject to discipline with respect to the underlying conduct or violation. You are entitled to make the report on a confidential and anonymous basis. To the extent an investigation must be initiated, the company will keep confidential any report you make to the Corporate Compliance Officer or another member of the Compliance Committee to the extent required by applicable law.

In addition, if you in good faith report a suspected violation under the Code which you reasonably believe constitutes a violation of a federal statute by the company, or its agents acting on behalf of the company, to a federal regulatory or law enforcement agency, you may not be reprimanded, discharged, demoted, suspended, threatened, harassed or in any manner discriminated against in the terms and conditions of your employment for reporting the suspected violation, regardless of whether the suspected violation involves you, your supervisor or senior management of the company.

Associates are encouraged to pursue all internal reporting channels through completion and reasonably await and consider the results of all internal investigations prior to reporting matters outside of the company. We have instituted the procedures described in this Code, including procedures to make anonymous submissions (a form of internal report), to facilitate the use of internal investigations.

Individuals should also consider leaving, but are not required to leave, their name or a contact number when submitting a report. Such information may facilitate a more thorough and efficient investigation. The Corporate Compliance Officer will strive to maintain the integrity and confidentiality of all compliance-related communications. However, in certain circumstances, the identity of the person reporting the issue may become known or may need to be revealed, particularly if federal or state enforcement authorities become involved in the investigation. The company cannot guarantee confidentiality when material evidence of a violation of the law is disclosed or if the person is identified during the normal course of an investigation.

Nothing in the Code prohibits you from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. You do not need the prior authorization of the Corporate Compliance Officer, the Compliance Committee, the Audit Committee or any other party to make any such reports or disclosures and you are not required to notify the company that you have made such reports or disclosures.

Q: How are suspected violations investigated under the Code?

A: When a suspected violation is reported to the Hotline, the Corporate Compliance Officer or a member of the Compliance Committee, the Compliance Committee will gather information about the allegation by interviewing the associate reporting the suspected violation, the associate who is accused of the violation and/or any co-workers or associates of the accused associates to determine if a factual basis for the allegation exists. The reporting associate's immediate supervisor will not be involved in the investigation if the reported violation involved that supervisor. The company will keep the identity of the reporting associate confidential to the fullest extent required by applicable law.

If the report is not substantiated, the reporting associate will be informed and at that time will be asked for any additional information not previously communicated. If there is no

additional information, the Corporate Compliance Officer will close the matter as unsubstantiated.

If the allegation is substantiated, the Compliance Committee will make a judgment as to the degree of severity of the violation and the appropriate disciplinary response. In more severe cases, the Compliance Committee will make a recommendation to the Board of Directors of the company for its approval. The Board's decision as to disciplinary and corrective action will be final. In the case of less severe violations, the Corporate Compliance Officer may refer the violation to the individual's supervisor, the Human Resources Department, the Corporate Compliance Officer or any member of the Compliance Committee for appropriate disciplinary action.

The Compliance Committee shall provide a summary of all matters considered under the Code to the Board of Directors or a committee thereof at each regular meeting thereof, or sooner if warranted by the severity of the matter.

Q: Do I have to participate in any investigation under the Code?

A: Your full cooperation with any pending investigation under the Code is a condition of your continued relationship with the company. The refusal to cooperate fully with any investigation is a violation of the Code and grounds for discipline, up to and including termination.

Q: What are the consequences of violating the Code?

A: As explained above, associates who violate the Code may be subject to discipline, up to and including termination of employment. Associates who violate the Code may simultaneously violate federal, state, local or foreign laws, regulations or policies. Such associates may be subject to prosecution, imprisonment and fines, and may be required to make reimbursement to the company, the government or any other person for losses resulting from the violation. They may be subject to punitive or treble damages depending on the severity of the violation and applicable law.

Q: What if I have questions under the Code or want to obtain a waiver under any provision of the Code?

A: The Corporate Compliance Officer and any member of the Compliance Committee can help answer questions you may have under the Code. Particularly difficult questions will be answered with input from the Compliance Committee as a whole. In addition, Section IX of the Code provides information on how you may obtain a waiver from the Code; waivers will be granted only in very limited circumstances. You should never pursue a course of action that is unclear under the Code without first consulting the Corporate Compliance Officer or the Compliance Committee, and if necessary, obtaining a waiver from the Code.

APPENDIX A

ASSOCIATE'S AGREEMENT TO COMPLY

I have read the Pieris Pharmaceuticals, Inc. Corporate Code of Conduct and Ethics and Whistleblower Policy(the "Code"). I have obtained an interpretation of any provision about which I had a question. I agree to abide by the provisions of the Code. Based on my review, I acknowledge that

_____ To the best of my knowledge, I am not in violation of, or aware of any violation by others of, any provision contained in the Code;

OR

_____ I have made a full disclosure on the reverse side of this acknowledgement of the facts regarding any possible violation of the provisions set forth in the Code.

In addition, I understand that I am required to report any suspected or actual violation of the Code, and that I may make such reports on a fully anonymous basis through the mechanisms described in this Code. I understand that I am required to cooperate fully with the company in connection with the investigation of any suspected violation. I understand that my failure to comply with the Code or its procedures may result in disciplinary action, up to and including termination.

By:_____ Date:_____

Name (Please print):

Department/Location:

Exhibit 21.1

Subsidiaries

Entity	Jurisdiction of Organization
Pieris Pharmaceuticals GmbH	Germany
Pieris Australia Pty Limited	Australia
Pieris Pharmaceuticals Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 Nos. 333-211844, 333-212439, 333-226725 and 333-235350),
(2) Registration Statement (Form S-8 No. 333-204487) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan,
(3) Registration Statement (Form S-8 No. 333-209308) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan and Inducement Stock Option Award for Louis Matis, M.D.,
(4) Registration Statement (Form S-8 No. 333-213771) pertaining to the Pieris Pharmaceuticals, Inc. 2016 Employee, Director and Consultant Equity Incentive Plan,
(5) Registration Statement (Post-Effective Amendment to FORM S-1 ON FORM S-3 No. 333-202123),
(6) Registration Statement (Form S-8 No. 333-221497) pertaining to Inducement Stock Option Awards for Claude Knopf, Allan Reine, M.D, and Ingmar Bruns, M.D., Ph.D,
(7) Registration Statement (Form S-8 333-226733) pertaining to the Pieris Pharmaceuticals, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan,
(8) Registration Statement (Form S-8 333-226735) pertaining to the Pieris Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan,
(9) Registration Statement (Form S-8 333-233194) pertaining to the Pieris Pharmaceuticals, Inc. 2019 Employee, Director and Consultant Equity Incentive Plan; and
(10) Registration Statement (Form S-8 333-234625) pertaining to the Non-Qualified Stock Option Agreement, dated August 30, 2019.

of our reports dated March 13, 2020, with respect to the consolidated financial statements of Pieris Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Pieris Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Pieris Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 13, 2020

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Stephen S. Yoder, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 13, 2020

/s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President (principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Thomas Bures, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 13, 2020

/s/ Thomas Bures

Thomas Bures

Title: VP Finance and Treasurer (principal financial officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2019 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 13, 2020

/s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President
(principal executive officer)

Exhibit 32.2

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2019 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 13, 2020

/s/ Thomas Bures

Thomas Bures

Title: VP Finance and Treasurer
(principal financial officer)