Annual Report 2014

pieris PHARMACEUTICALS

Dear Shareholders, Employees and Friends,

2014 was a monumental year for Pieris in our pursuit to pioneer new, safe, and efficacious medicines by leveraging our proprietary Anticalin® drug discovery platform for therapeutic proteins. We made key advances with our pipeline, achieved significant and validating milestones with our partners, and transitioned from a private to publically traded company. The fundamentals of our company and our technology have never been more secure. The accomplishments of the past year have enabled us to raise our sights for the next twelve months. We will remain focused on our internal pipeline and our external partnerships, alike, while expanding our presence in the US.

Through our Anticalin therapeutics protein platform, we have isolated, characterized, and continue to develop several drug candidates addressing substantial markets where we believe our products will offer specific and significant value for patients. In November we initiated a Phase 1 study for PRS-080, an Anticalin designed to treat anemia stemming from functionally iron-deficient patients with chronic kidney disease. This is our second Anticalin to enter human trials, bringing additional clinical validation to this class of drugs. In addition, we demonstrated proof-of-concept in preclinical models and feasibility of pulmonary delivery for PRS-060, an Anticalin against IL4RA in development for the large group of patients suffering from moderate to severe asthma.

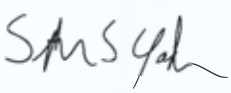
Our other pipeline programs include the PRS-300 Series, highly innovative multispecific candidates in immuno-oncology. The immunomodulatory targets that we are pursuing include a variety of immune checkpoints, both inhibitory and co-stimulatory. We isolated several Anticalin lead molecules against myriad immune checkpoints and have generated initial *in vitro* preclinical data demonstrating molecule stability and target engagement. With well-behaved multispecific molecules in hand, our focus will increasingly shift to elucidating new biology in our quest to develop differentiated drugs that can address patients not responding to today's therapies.

The promise of our Anticalin platform continues to drive successful partnerships, and 2014 was a very productive year for us and our collaborators. We received five milestone payments totaling over $3 million as a result of our collaborations with Sanofi Group and Daiichi-Sankyo. Our partnerships are and will continue to be an important part of our strategy as they provide non-dilutive capital, as well as additional preclinical and eventual clinical data sets for Anticalin proteins.

Lastly, we successfully completed an alternate public transaction in December and we began trading under the symbol PIRS on the OTC markets. Concurrent with this transaction, we completed a private placement raising approximately US $13.6 million in gross proceeds, significantly strengthening our balance sheet and providing us with the capital to advance our proprietary pipeline of promising drug candidates.

As always, I want to take this opportunity to thank our employees for their hard work and dedication. I also want to thank our shareholders for their commitment to our mission. 2015 will build on the momentum of 2014 as we expand our operations into the US and access top talent in the world's leading biotech market. We anticipate additional milestones within our partnerships and continued advancement of our pipeline and look forward to keeping you informed of our progress.

Sincerely,



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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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: 333-190728

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.)**
Lise-Meitner-Strasse 30, Freising-Weihenstephan, Germany	**85354**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code +49 81 6114 11400

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

Title of each class	**Name of each exchange on which registered**
None	**N/A**

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

None
(Title of class)

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

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

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐

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

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

As of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's common stock.

As of March 27, 2015, the registrant had 29,429,522 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on June 30, 2015.

TABLE OF CONTENTS

Forward Looking Statements

This Annual Report on Form 10-K contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties, principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "suggests," "future," "likely," "goal," "plans," "potential," "projects," "predicts," "should," "would," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors" or elsewhere in this Annual Report on Form 10-K, which may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ materially. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

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

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

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "our Company", "the Company", "Pieris", "we", "us", and "our" refer to Pieris Pharmaceuticals, Inc., a Nevada corporation, and its consolidated subsidiary, and the term "Pieris Operating" refers to Pieris AG, a company organized under the laws of Germany that, through a share exchange transaction completed on December 17, 2014, has become our wholly owned subsidiary.

Pieris effected a forward stock split of its capital stock at the ratio of 2.272727-for-1 on December 5, 2014. Unless the context indicates or otherwise requires, all share numbers and share price data included in this Annual Report on Form 10-K have been adjusted to give effect to this forward stock split.

Currency Presentation and Currency Translation

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

The functional currency for our operations is 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 other comprehensive income.

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. $1.2101 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2014.

PART I

Item 1. BUSINESS

Corporate History

General

Pieris was incorporated under the laws of the State of Nevada on May 24, 2013 with the name "Marika Inc." Prior to the Acquisition, as defined below, Pieris pursued a business of an errand concierge service online marketplace. Pieris filed a registration statement on Form S-1 (File No. 333-190728) that was declared effective by the Securities and Exchange Commission, or SEC, on January 28, 2014, and sold an aggregate of 2,500,012 shares of its common stock (on a post forward stock split basis) under that registration statement.

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

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

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

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

On December 17, 2014, Pieris entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain accredited investors, or the Investors, providing for the issuance and sale to such investors of an aggregate of 6,779,510 shares of our common stock in a private placement offering conducted through a series of closings occurring on December 17, 18 and 23, 2014, at a purchase price per share of $2.00 and for aggregate gross proceeds to us of $13.56 million, or the Private Placement. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.04 million. Northland Securities, Inc. and Katalyst Securities, LLC served as co-exclusive placement agents, or the Placement Agents, for the Private Placement. The Securities Purchase Agreement also contains certain anti-dilution provisions. Those anti-dilution provisions provide that, subject to certain exceptions, if we issue and sell equity securities or equity-linked or related securities at a purchase price per share of lower than $2.00 within the 180-day period following December 17, 2014, each Investor in the Private Placement shall be entitled to receive such number of additional shares of our common stock as they would have received had such lower purchase price per share been applicable in the Private Placement.

At the closings of the Private Placement we issued to the Placement Agents and their designees, warrants, or the Placement Warrants, to acquire up to 542,360 shares of our common stock at an exercise price of $2.00 per share. Each of the Placement Warrants is exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance.

In connection with the Private Placement, we also entered into a registration rights agreement, or the Registration Rights Agreement, with the Investors, the former stockholders of Pieris Operating and the holders of Placement Warrants. Pursuant to the terms of the Registration Rights Agreement, the Company agreed to file with the SEC, within 90 days following December 17, 2014, a registration statement to register for resale all of the 6,779,510 shares of the Company's common stock issued in the Private Placement, as well as an additional 20,000,000 shares of our common stock which the Company issued to former stockholders of Pieris Operating in connection with the closing of the Acquisition, and an additional 542,360 shares of common stock issuable to holders of the Placement Warrants. The Company also agreed to use commercially reasonable efforts to have such registration statement declared effective within 180 days following the date of its filing with the SEC. If the registration statement is not declared effective on or before the applicable effectiveness deadline or ceases to be effective during the required effectiveness period, except as permitted under the Registration Rights Agreement, the Company will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock on every monthly anniversary of such failure and prorated for any portion of a month, until it is cured or all of such selling stockholder's securities to be registered hereunder have been or may be sold without restriction pursuant to Rule 144. Furthermore, if the Company fails to timely file reports required to be filed by us pursuant to Section 13(a) or 15(d) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Company will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock. Notwithstanding the foregoing, the Company will not be obligated to make any such payments with respect to any of the securities to be registered thereunder that we are unable to register due to limits imposed by the SEC's interpretation of Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act. Under the Registration Rights Agreement, subject to exception in certain circumstances or pursuant to the Acquisition, as applicable, 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 pursuant to Rule 144 or may be sold without restriction pursuant to Rule 144. If there is not an effective registration statement covering the resale of the securities to be registered by such registration statement at any time prior to December 17, 2015, then the selling stockholders will have "piggyback" registration rights with respect to any such securities that are not eligible for resale pursuant to Rule 144 without volume or manner of sale restrictions in connection with any other registration statement we determine to file that would permit the inclusion of those shares.

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

Emerging Growth Company and Smaller Reporting Company Status

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

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

- An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.
- An emerging growth company is exempt from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and financial statements, commonly known as an "auditor discussion and analysis."
- An emerging growth company is not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders.
- Neither an emerging growth company nor a smaller reporting company is required to comply with the requirement of auditor attestation of internal controls over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act of 2002.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced financial statement disclosure in registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

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

Business Overview

We are a clinical-stage biopharmaceutical company dedicated to the discovery and development of our Anticalin® class of biotherapeutics for patients with diseases in which we believe there is high unmet medical need.

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

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

We believe that the drug-like properties of the Anticalin® drug class were demonstrated in a Phase Ib clinical trial in solid tumor patients of our anti-VEGF-A Anticalin-branded drug candidate, PRS-050, designed to inhibit blood vessel growth in solid tumors. VEGF-A is a protein that induces growth of blood vessels, and anti-VEGF-A drug aim to inhibit the blood supply to solid tumors. In a multi-ascending dose trial performed under governance by the German Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM*), PRS-050 was shown to be generally safe and well-tolerated, and we were not able to detect any anti-drug antibodies, or ADAs, following administration of a total of 144 doses with five or more doses to 17 patients. We believe that these results demonstrated that there was no apparent immune response against PRS-050. Furthermore, dose-proportional pharmacokinetics, pharmacology and biomarker activity were observed in the trial, which we believe demonstrates that PRS-050 engaged with its intended target VEGF-A in those patients. Despite these results, we, decided not to advance PRS-050 based on our belief that PRS-050's mode of action (the way in which it functions in the body, namely, antagonizing VEGF-A) was not sufficiently differentiated over the modes of action of already-marketed therapies, such as bevacizumab and aflibercept, to create enough economic value in the drug market to support continued development of PRS-050 as a competitive product candidate. While we have not advanced development of PRS-050 since that time for the aforementioned strategic and business reasons, we believe that the positive results from this clinical trial generally support continued investment in our Anticalin drug candidates.

Our core Anticalin® technology and platform was developed in Germany, and we have partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India. These include existing agreements with Daiichi Sankyo Company Limited, or Daiichi Sankyo, and Sanofi Group, or Sanofi, pursuant to which our Anticalin platform has consistently achieved its development milestones. We have discovery and preclinical collaboration

and service agreements with both academic institutions and private firms in Australia, which increasingly are being handled through Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris Operating. We also intend to establish a greater U.S. presence and take advantage of the U.S. capital markets, additional potential corporate partners, and the broad expertise found in the biotechnology industry in the United States.

Our current development plans focus mainly on two drug candidates, PRS-080 and PRS-060. PRS-080 is an Anticalin® protein that binds to hepcidin, a natural regulator of iron in the blood. An excess amount of hepcidin can cause functional iron deficiency, or FID, which often cannot be treated adequately with iron supplements and can lead to anemia. PRS-080 has been designed to target hepcidin for the treatment of FID in anemic patients with chronic kidney disease, or CKD, particularly in end-stage renal disease patients requiring dialysis. We believe that by blocking the actions of hepcidin, PRS-080 will serve to address anemia by mobilizing iron for incorporation into red blood cells. Furthermore, we engineered PRS-080 to have a half-life of less than a week, so that following administration, it is expected to clear from the human body in a much shorter timeframe than antibodies, which typically have a half-life of two weeks or greater. We believe a shorter residence time in the body may be a superior approach for countering excess hepcidin, as physiological levels of hepcidin in these patients are relatively high (nanomolar concentration), and in theory such high concentrations will quickly saturate an administered binding drug. As a result, frequent administration of a drug may be required in order to sufficiently antagonize, or suppress the effect of, the target. The longer residence time of a monoclonal antibody, or mAb, could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. We initiated a Phase I clinical trial with PRS-080 in healthy volunteers in November 2014. The trial is currently enrolling subjects and we expect to report the data from this trial by the end of 2015.

The second Anticalin® drug candidate, PRS-060, binds to the IL-4 receptor alpha-chain (IL-4RA), thereby inhibiting IL-4 and IL-13, two cytokines (small proteins mediating signaling between cells within the human body) known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases. The small size and biophysical stability of PRS-060 enable direct delivery to the lungs, such as through the use of an inhaler, which we believe will enable high concentrations of the drug candidate at the locus of disease at substantially lower doses than would be achievable with antibodies that are systemically delivered. Further, PRS-060 has a short systemic residence time in the body which we believe may avoid undesired target engagement outside of the desired area in the lungs. PRS-060 is currently in preclinical development, and we intend to begin a Phase I clinical trial with PRS-060 in 2016.

We are also developing PRS-110 and our 300-Series in oncology. PRS-110 is a monovalent antagonist (a polypeptide molecule with one target- binding domain) that is designed to block cMet activity, independent of whether induced by hepatocyte growth factor, or HGF, the natural ligand for cMet, or mediated through intrinsic ligand-independent activity. cMet is a receptor tyrosine kinase, a well-known high-affinity cell surface receptor that transmits signals into the cell when a corresponding ligand binds to it, which is essential for embryonic development and wound healing and has been associated with several different cancers, including renal, gastric and lung carcinomas, central nervous system tumors and sarcomas. We have shown in preclinical *in vivo* studies that PRS-110 blocks both ligand-dependent and ligand-independent activity while also being devoid of any activating (agonistic) activity, likely due to the monovalent manner in which it engages cMet. Preclinical studies have also shown that PRS-110 both inhibits receptor activation and leads to receptor removal, highlighting its novel mechanism of action and potential for the treatment of cMet-driven tumors. In October 2013, we entered into a development and license agreement with Cadila Healthcare Limited (Zydus Cadila), or Zydus, for the preclinical development of PRS-110, pursuant to which we share certain commercial rights to PRS-110 with Zydus. For more information about the Zydus agreement, see "—Strategic Partnerships".

Our second set of oncology drug candidates is our 300-Series "platform within a product" opportunity in immuno-oncology. The 300-Series Anticalin® proteins target checkpoint proteins and define a variety of multifunctional biotherapeutics that genetically link an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein. Checkpoint proteins are proteins that help the development of an immune

response or downregulate the response, for example when an infection is eliminated. We are conducting preclinical experiments on a number of 300-Series lead candidates and intend to choose a candidate by the end of 2015 for eventual clinical trials in oncology. The 300-Series platform is modular, which we believe will permit rapid evaluation of unique combinations of validated tumor targets and immunomodulatory checkpoint proteins. For example, one panel of 300-Series Anticalin proteins, currently being evaluated in the preclinical stage of experiments, is directed with specificity and subnanomolar affinity against CTLA-4, a protein receptor that downregulates the immune system and which is found on the surface of T cells, regulating T cells at their stage of initial activation, in effect turning "off" the attacking nature of the T cells. T cells are a type of white blood cell that play several central roles in the immune system. Inhibiting CTLA-4, and thus allowing T cells to attack cancer cells, has been validated with other biologics, including ipilimumab, which is marketed by Bristol-Myers Squibb as Yervoy.

In addition, in November 2013, Pieris Operating entered into a joint development and license agreement with Stelis BioPharma Private Limited, a subsidiary of Strides Arcolab Limited, or Stelis, establishing a collaboration for clinical development and commercialization of certain of our proprietary products, primarily focusing on use in ophthalmological applications. Under the terms of the agreement, we contribute certain proprietary assets to the development project, and Stelis agrees to establish a production process for preclinical and clinical supplies of product and to perform certain preclinical and a first-in-human clinical study. We agreed that upon reaching certain development stages for a product, we and Stelis would discuss the possible formation of a joint venture to further develop and commercialize such product. We believe the agreement pairs our drug discovery capabilities with Stelis' bio-manufacturing and clinical development expertise. For more information about the Stelis agreement, see "—Strategic Partnerships" below.

Strategy

Our goal is to become a fully integrated biotechnology company by developing Anticalin® therapeutics against a variety of targets in diseases and conditions with high unmet medical need, and later developing and commercializing our products. We intend to take advantage of our operational experience in technology development and our history of successful partnerships and collaborations to gain access to additional partnerships that will help provide us the experience we need to bring Anticalin drug candidates to market in a number of indications. We intend to engage with partners for many of our programs in a combination of geographic and indication-based arrangements to maximize our business opportunities. We also intend to retain certain development and commercial rights on selected products as our experience in drug development grows. Key elements of our strategy include:

- ***Continue to build our platform by entering into new partnerships and license and collaborative arrangements and advancing our currently-partnered programs.*** We have already entered into partnership and collaborative arrangements with pharmaceutical companies in a diverse range of therapeutic areas and geographies. We have active partnerships with global pharmaceutical companies, such as Allergan, Sanofi and Daiichi Sankyo, and have entered into partnership arrangements with two pharmaceutical companies based in India, Zydus and Stelis. Together with these partners, we intend to advance multiple drug candidates through preclinical studies and to select further drug candidates for clinical development in the future. We will also continue to seek to engage with new pharmaceutical partners that can contribute funding, experience and marketing ability for the successful development and commercialization of our current and future drug candidates.
- ***Advance our lead drug candidate, PRS-080, against hepcidin in clinical trials.*** We intend to continue the recently initiated Phase I clinical trial with PRS-080 in healthy volunteers, and anticipate being able to report the data from this trial by the end of 2015. Depending on the results of the trial, thereafter pursue biomarker-driven efficacy trials in CKD patients suffering from FID-anemia.
- ***Bring other drug candidates in our proprietary pipeline into clinical trials.*** We have a strong preclinical pipeline of Anticalin drug candidates in diverse indications such as severe asthma

(PRS-060) and immuno-oncology (300-Series). We will continue to move forward with preclinical and discovery work on these drug candidates with the goal of advancement into clinical trials on a data-driven basis.

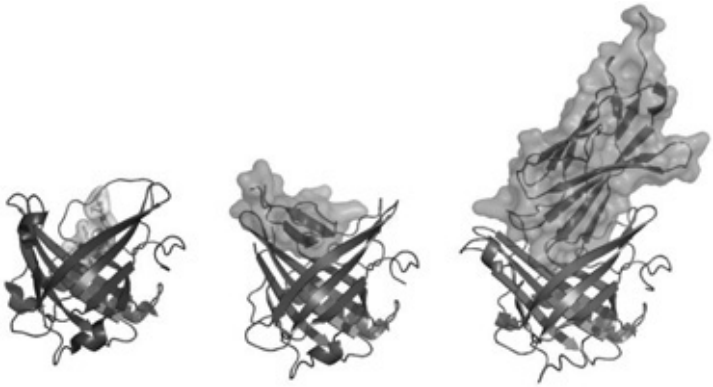
- ***Pursue and broaden opportunities for our Anticalin technology.*** We intend to continue to identify, vet and pursue opportunities to develop novel Anticalin therapeutics for oncology, pulmonary disease and a variety of additional diseases, as we continue to improve on the Anticalin platform technology.
- ***Develop an even broader geographic base.*** Through our partnerships with pharmaceutical companies in Europe, Asia and the United States, and through our preclinical and clinical collaboration arrangements in Australia, we have already created a broad set of international contacts that allows us to seek diverse opportunities in the global biotechnology industry. By seeking to establish a greater presence in the United States, we intend to further diversify our contacts and opportunities and take advantage of the strengths of the U.S. capital markets, drug development capabilities and partnership opportunities.

Anticalin platform technology

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

Anticalin® proteins are created from either tear lipocalin, found in human tear fluid, or NGAL lipocalin, a protein involved in the innate immune system, by making discreet mutations in the genetic code for the binding regions. These mutations have the potential to lead to highly specific, high-affinity binding for both small and large molecular targets. Random mutations are introduced at pre-defined positions involved in endogenous ligand engagement, creating exponentially diverse pools of Anticalin proteins, the most potent and well behaved of which are selected and optimized in a customized manner through *in vitro* selection. Using techniques such as phage display, a successful technique in antibody-based drug discovery, to build and refine antibody libraries, the ability to introduce diversity and then select for the best binders among a large pool of Anticalin proteins gives us the opportunity to select Anticalin proteins for a wide variety of targets. The flexibility inherent in the Anticalin proteins' cup-like structure allows us to choose both small-molecule targets that fit inside the 'cup' as well as larger protein targets that can be bound by the Anticalin proteins' outward-facing arms. Our Phase Ib trial for PRS-050 indicated that Anticalin proteins may be non-immunogenic and thereby have the potential to exhibit a favorable safety profile.

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



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

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

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

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

- *Small size and biophysical stability*. Anticalin proteins are small in size and are monomeric. Therefore, we believe Anticalins are generally more stable biophysically than tetrameric monoclonal antibodies, potentially enabling unique routes of administration to target diseases, such as pulmonary delivery. Higher-molecular-weight entities such as antibodies are often too large to be delivered effectively

through these methods. We believe Anticalin proteins will also be less expensive to manufacture than antibodies due to their lower molecular weight and less bulky structure as well as the ability to use the prokaryotic-based manufacturing systems, a less costly manufacturing system than mammalian cell-based manufacturing systems.

- *Optimization of half-life*. Anticalin proteins can be engineered to have a half-life that is optimal for the indication area and a desired dosing schedule. Antibodies typically have half-lives of two weeks or longer, whereas Anticalin proteins can be engineered to have half-lives from hours to weeks, depending on the half-life extension technology employed, if any. This optionality allows us to exert greater control over the amount of circulating Anticalin protein in the blood and the amount of time such Anticalin proteins circulate in the blood, depending on the underlying biology we are trying to address.
- *Modular platform for higher-order multispecificity and avoidance of cross-linking*. Our Anticalin technology is modular, allowing for monovalent or multivalent target engagement, including multispecificity within a single protein. We believe that a monovalent "backbone" is an advantage in situations where pure antagonism of certain cellular receptors is desired. The dual-binding nature of monoclonal antibodies, which have two "arms," can be a disadvantage in cases when the antibodies bind to and cross-link cell-surface receptors. Such cross-linking often leads to undesirable activation of the cells bearing those receptors. Single-action (monovalent) Anticalin proteins have only a single binding site and are thus not subject to cross-linking. Further, when it is called for by the biology we are addressing, we can create multispecific Anticalin proteins that can simultaneously bind (i) two or more different targets or (ii) different epitopes, the specific piece of an antigen to which an antibody binds, on the same target by genetically linking Anticalin proteins with distinct specificities on a common cDNA strand. We believe this multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as killing cancer cells. Unique Anticalin proteins can be pieced together and undergo simultaneous target engagement as a single fusion protein, without generally compromising on manufacturability.

We believe that drug-like properties of the Anticalin® drug class were demonstrated in a Phase Ib clinical trial for PRS-050 in solid tumor patients, our anti-VEGF-A Anticalin-branded drug candidate designed to inhibit blood vessel growth in solid tumors. Although we are not advancing the development of PRS-050 in oncology for strategic and business reasons, we were able to demonstrate in 26 patients with advanced solid tumors that this drug candidate engaged its target with nanomolar affinity, did not generate any detectable ADAs, and has an activity that can be confirmed by biomarker activity, target engagement assays and known on-target effects such as hypertension. In this trial, 17 patients received five or more doses of PRS-050. We believe that the positive results from the Phase Ib clinical trial for PRS-050 lends support to the future success of our drug candidates currently in development.

Implementation of our Anticalin Platform Technology: Our Drug Candidates

Pipeline

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

Product Candidate and Target	Indication	Stage of Development (Research / Preclinical / Phase1)	Upcoming Milestone	Commercial Rights
PRS-080 targeting Hepcidin	FID, Anemia of chronic kidney disease		▪ Recruitment of healthy subjects into Phase I clinical study ▪ Data from Phase I in healthy subjects expected end 2015	Pieris
PRS-060 targeting IL-4RA	Asthma		▪ Expect to complete preclinical phase in 2016 ▪ Planned Phase I clinical study to begin in 2016	Pieris
PRS-110 targeting cMet	Oncology		▪ Zydus conducting preclinical studies ▪ Expect to complete preclinical phase in 2016	Pieris and Zydus
PRS-300 targeting checkpoint proteins	Immuno Oncology		▪ In preclinical phase	Pieris

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

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

PRS-080 has been designed to target hepcidin for the treatment of FID in anemic patients with CKD, particularly in end-stage renal disease patients requiring dialysis, to allow them to mobilize iron that is trapped in iron storage cells for use in the creation of red blood cells. We have also engineered PRS-080 to have a half-life of less than a week, so that following administration, it is expected to clear from the human body in a much shorter timeframe than antibodies, which typically have a half-life of two weeks or greater. This half-life was achieved by covalently linking PRS-080 to a specific polyethylene glycol, or PEG, in order to extend the serum half-life of the combined molecule to desirable levels. Since hepcidin is constantly produced by the body, we believe that a frequent, e.g. once per week, dosing interval will be optimally suited to interfere with hepcidin function. A half-life of about three days and a shorter residence time than mAbs is then in turn more compatible with the dosing schedule. A longer mAb-like residence time is not seen as advantageous, but rather could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. We initiated a Phase I clinical trial with PRS-080 in healthy volunteers in November 2014. The trial is currently enrolling subjects and is being conducted in accordance with German law

at a clinical site in Neu-Ulm, Germany, that belongs to Nuvisan GmbH, our contract research organization, or CRO. The results from this trial, which we expect to have by the end of 2015, are intended to provide clinical-trial support for subsequent applications in the U.S.

Chronic kidney disease

According to the American Kidney Fund, approximately 31 million individuals in the United States have CKD (Stages 1-5). The proportion of CKD patients with anemia increases with the severity and stage of CKD, however according to a September 2013 competitive landscape report conducted by Tech Atlas Group, overall rates of individuals with anemia among the CKD population are approximately 30%, and according to a 2004 study by McClellan et al., Current Medical Research and Opinion, approximately 47% of the CKD patients studied were found to be anemic. Extrapolating these percentages based on the CKD population of 31 million individuals, we believe that approximately 9.3 to 14.6 million individuals in the United States with CKD are anemic. CKD (Stage 5), also known as End-Stage Renal Disease, or ESRD, is the final stage of chronic kidney disease with approximately 0.64 million patients in the US as of December 31, 2012 according the U.S. Renal Data System, USRDS 2014 Annual Data Report. The Tech Atlas Group report also estimates that approximately 70%, or approximately 0.45 million, of CKD (Stage 5) patients suffer from anemia. Anemia related to CKD is currently treated by injectable recombinant protein erythropoiesis, or red blood cell production, stimulating agents, or rESAs—including Epogen, Aranesp, and Procrit—with iron supplementation or a red blood cell transfusion. Based on the reported revenues of companies that market and sell rESAs, we believe that global sales of injectable rESAs were $6.3 billion in 2012, the vast majority of which were for renal indications.

Anemia and functional iron deficiency in the CKD population

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

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

Challenges in using conventional therapy

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

Our potential solution: binding hepcidin with PRS-080

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

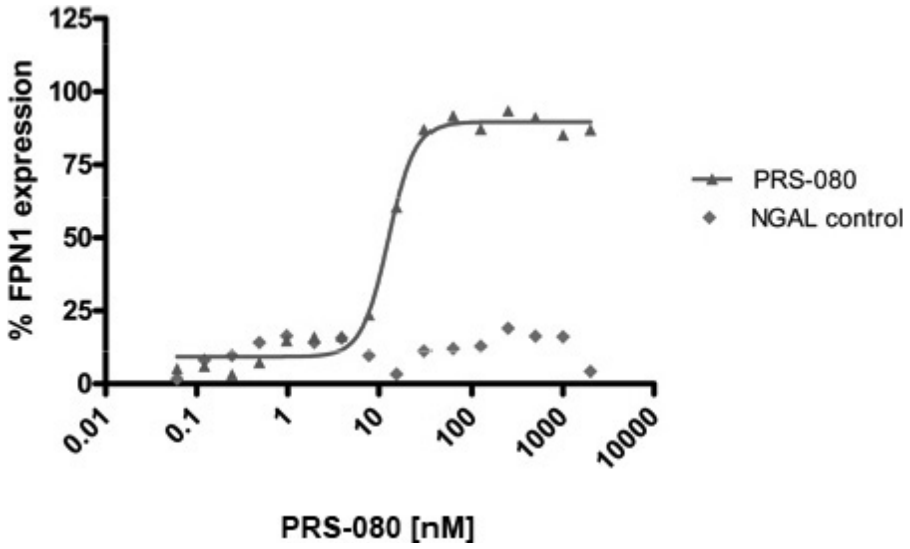
In patients suffering from anemia of CKD, and specifically in patients with FID, hepcidin is frequently produced by the body in abnormally large amounts. Therefore, we believe that the best way to inhibit its function is to administer an inhibitor frequently, such as once a week. Our approach will use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

Preclinical data

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

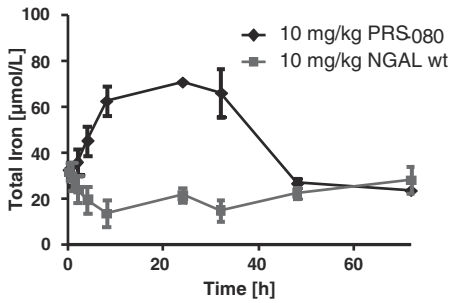
Hepcidin binds to ferroportin and induces its internalization and subsequent degradation, thus disabling iron mobilization from cells. PRS-080 binds strongly to hepcidin and inhibits its activity as shown in potency assays. These in vitro potency studies showed that the hepcidin-induced internalization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

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

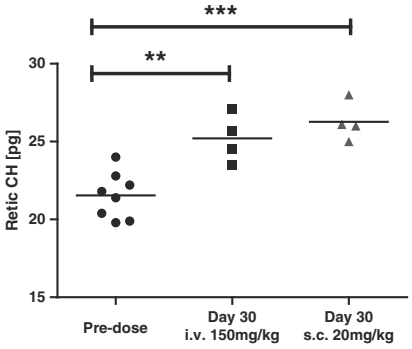


We then studied the functional consequences of hepcidin inhibition on iron mobilization in cynomolgus monkeys. A dose of 1 mg/kg PRS-080 produced a robust, transient and reversible increase in total iron levels from approximately 36 µM at baseline to 52 µM after 8 hours. Doses higher than 1 mg/kg elevated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

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



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



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

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

Phase I trial design

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

The first clinical trial enrolling patients is planned to be initiated in 2015. We first plan to enroll CKD patients to study pharmacokinetics in a single-dose format. We plan to subsequently dose repeatedly and study the effects of PRS-080 administration on iron mobilization and erythropoiesis in CKD patients.

Based on the results of the initial trials, our current intention is to design additional trials to examine dose response and longer treatment periods. Endpoints may include levels of circulating hemoglobin, which corresponds to the degree to which anemic patients with FID respond to PRS-080. Titration of intravenous iron and rESA doses will also be implemented in future trials. We intend to incorporate and utilize U.S. clinical sites in connection with such additional studies. We plan to submit an Investigational New Drug, or IND, application to the U.S. Food and Drug Administration, or FDA, for PRS-080 in 2017.

PRS-060 targeting IL-4RA in asthma

PRS-060 is an Anticalin® drug candidate targeting IL-4RA, a cell surface receptor expressed on immune cells in the lung epithelium and mucosal layer. IL-4RA is specific to the circulating cytokines IL-4 and the closely related cytokine IL-13, both key drivers of the immune system that induce differentiation of naïve helper T cells to type 2 helper T cells, or Th2. PRS-060 is derived from human tear lipocalin, has picomolar affinity for human IL-4RA (20 pM) and has a favorable stability profile. We showed *in vitro* that PRS-060 can inhibit the activity of both IL-4 and IL-13. We have formulated PRS-060 supporting a delivery through inhalation, and we are actively preparing to carry out bioprocess optimization in preparation for Current Good Manufacturing Practice, or cGMP, manufacturing and preclinical safety and tolerability studies. Pending the results of our preclinical studies, we intend to pursue a first-in-man clinical trial for PRS-060 in 2016. Some of the development of PRS-060 is conducted in Australia, where we intend to access leading Australian pulmonologists for potential patient recruitment and to seek up to 40% or more in tax refunds from the Australian government in connection with research and development expenses related to PRS-060. We believe PRS-060 represents a first-in-class inhaled biologic for the treatment of asthma.

Asthma market

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

Challenges in using conventional therapy

According to a 2012 Artisan Health Care Consulting analysis, as of 2011 asthma affects approximately 195 million people in the U.S., Europe, Japan, Brazil, Russia, India and China. The analysis determined that approximately 16%, or 32 million, of the group studied were considered to have moderate and severe uncontrolled asthma, while approximately 9%, or 19 million, of the group studied were considered to have moderate and severe uncontrolled asthma with an elevated Th2 signature. Extrapolating from these percentages to the global asthma population of 300 million individuals, we believe that approximately 48 million asthma sufferers worldwide are considered to have severe, persistent or uncontrolled disease and a large percentage of these patients, approximately 28 million, display inflammatory exacerbations associated with Th2 immunity. Inflammation brought about by Th2 immunity is not addressed by standard asthma therapies. Standard therapies are not able to address such patients, symptoms or they develop resistance to the inhaled steroids, currently considered the standard of care.

The current standard of care for persistent, moderate to severe allergic asthma is omalizumab (Xolair from Roche). Omalizumab was approved for this condition in the United States in 2003. Outside of the United States, omalizumab is approved for severe asthma and it is currently the only biologic approved for asthma. Omalizumab works by binding to the immune mediator immunoglobulin E, or IgE, and inhibiting IgE-mediated activation of mast cells and basophils, types of white blood cells. It has also been shown to impact some diseases, such as asthma, that are driven by eosinophils, another important class of immune cells. However, patient response to omalizumab has been shown to be inconsistent, as reported in a publication by McNicholl and Heaney in 2008 in the journal *Core Evidence*, which explained that in only some studies did omalizumab improve lung function. Furthermore, general asthma symptoms are also typically unaffected by omalizumab. Finally, in 2007, the FDA issued a black box warning for omalizumab due to reported cases of anaphylaxis, a potentially life-threatening allergic reaction suffered by some patients who had taken the drug. Despite these shortcomings, in 2012, worldwide sales of omalizumab were reported by Roche to be $1.2 billion.

The next generation of therapies beyond omalizumab targets a broader range than just IgE mediated mechanisms. These approaches target other immune mediators, including IL-5, IL-4 and IL-13 (which act in concert on eosinophils, B-cells, epithelial cells, goblet cells and others) and CRTH2. Asthma is associated with high levels of eosinophils, immune cells that play a role in protecting the body against infection. The creation of eosinophils can be interrupted at the early stages, while the cells are still maturing. Multiple products are in development that target eosinophils. However, eosinophils are only one of many cell types and immune system components that are involved with the body's exaggerated inflammation response in asthma. Mast cells, basophils, goblet cells and other cells also play a role. These cells can be seen infiltrating the airways along with eosinophils, leading to the conclusion that more cell types are involved. We believe that targeting just one of these components is not likely to be as effective in resolving severe asthma as an approach that targets the broader Th2 (cell-mediated) pathway.

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

Another biologic in development for severe asthma is lebrikizumab, which blocks IL-13, a mechanism known to have a similar effect to that of dupilumab. Like dupilumab and other mediators of the Th2 pathway, lebrikizumab is a validating example for subcutaneously delivered Th2 intervention in treating uncontrolled asthmatics. In a 2011 publication in the New England Journal of Medicine, lebrikizumab was reported to improve lung function in severe asthma patients who were also receiving standard of care inhaled glucocorticoid therapy. At the same time, patients in the study who received lebrikizumab showed greater musculoskeletal side effects than patients receiving placebo. We believe that the ability to impact disease biology and improve lung function with biologics such as lebrikizumab is a promising result.

We believe that there could also be significant advantages to other routes of administration, such as inhalation, of biologics that target asthma through the Th2 pathway. If delivered by inhalation, such biologics could be dosed at much lower levels and may preferentially direct the therapy to the site of the disease, in this case the lung.

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

We propose to take PRS-060 forward into clinical trials first in healthy volunteers and then in severe asthma patients. These trials could accomplish two important goals: we could establish proof-of-concept for inhaled Anticalin® proteins, opening up a second route of administration for our drug candidates beyond intravenous or subcutaneous injection. And if, based on data, we are able to enter a proof-of-concept trial in these patients, we will attempt to demonstrate that PRS-060 can improve patient symptoms. We intend to begin a Phase I clinical trial for PRS-060 in 2016.

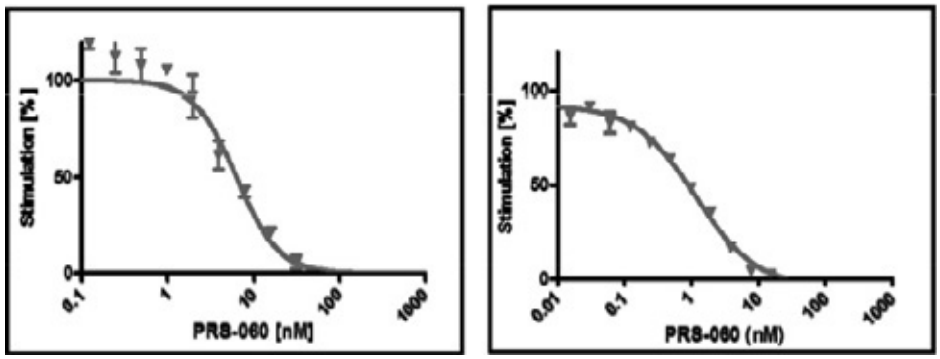
Advantages to inhalation as a route of administration for PRS-060

We have performed inhalation studies in mice and observed that systemic concentrations of PRS-060 are minimal when dosed by inhalation, as a result of low doses and short systemic residence time. This offers the

potential of a wider therapeutic window and possibly lower systemic side effects that may become prevalent with chronic, systemic Th2 interrogation. By our calculations, the dose of PRS-060 can be lower than the doses being used for the monoclonal antibodies dupilumab and lebrikizumab. Furthermore, we believe that PRS-060 can be produced at a lower cost of goods than monoclonal antibodies because we intend to use manufacturing procedures that employ bacterial expression systems, which generally provides a cost advantage over mammalian production systems, typically used for mAbs. Since dosing by inhalation is a common route of administration in asthma patients, it represents a more convenient dosage regimen for patients than dosing of antibodies by injection and would not need to be administered in a physician's office or other medical setting.

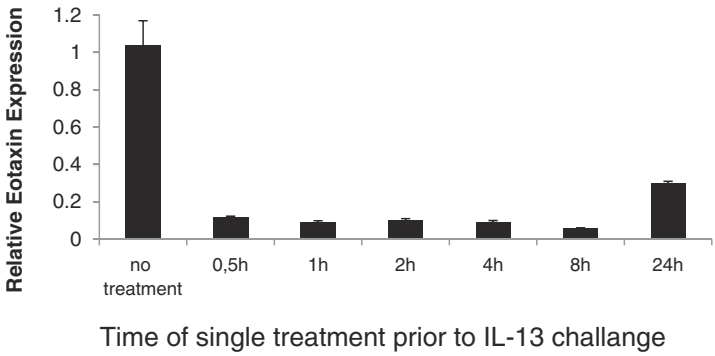
Preclinical data

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



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

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



When we administered IL-13 into the lung, inflammation was induced as determined by eotaxin expression, which was not inhibited when phosphate buffered saline, or PBS, was administered into the lung. In contrast to

the PBS administration, eotaxin expression and, as a result, inflammation was prevented when PRS-060 was administered into the lung before IL-13. As demonstrated in the above chart, the model showed the inhibitory potential lasts for up to 24 hours after PRS-060 administration.

Pipeline products: PRS-110 in cMet-related cancer

PRS-110 is an Anticalin® protein-based antagonist of cMet that blocks both ligand-dependent and ligand-independent activity. cMet is a receptor tyrosine kinase, a well-known high-affinity cell surface receptor which is essential for embryonic development and wound healing. Hepatocyte growth factor, or HGF, is the only known ligand of the cMet receptor, and upon HGF stimulation, cMet induces several biological responses that collectively give rise to a program known as invasive growth, which can in some cases trigger cancer formation or growth. cMet has been associated with several different cancers, including renal, gastric and lung carcinomas, central nervous system tumors and sarcomas. However, abnormal cMet activity, consisting of cMet amplification or mutation through cell overexpression or interaction with other membrane proteins or receptors, can also lead to HGF-independent tumor formation. Therefore, optimal targeting of the cMet pathway requires a drug with both ligand-dependent and ligand-independent efficacy. We have shown in preclinical in vivo studies that PRS-110 blocks both ligand-dependent and ligand-independent activity while also being devoid of any activating (agonistic) activity, likely due to the monovalent manner in which it engages cMet. Preclinical studies have also shown that PRS-110 inhibits receptor activation and leads to receptor degradation, highlighting its novel mechanism of action and potential for the treatment of cMet-driven tumors. Moreover, inhibition of other receptor tyrosine kinases, such as Bcr-Abl in chronic myeloid leukemia, c-kit in gastrointestinal stromal tumor and HER2 in breast cancer, by targeted therapies has been shown to have a significant clinical impact. Therefore, receptor tyrosine kinases targets such as cMet are currently a focus for drug discovery efforts in order to try to identify specific inhibitors. In October 2013, we entered into a development and license agreement with Zydus for the preclinical development of PRS-110, pursuant to which we share certain commercial rights to PRS-110. For more information about the Zydus agreement, see "—Strategic Partnerships".

Several experimental drugs targeting various aspects of the cMet pathway, including both small molecule drugs and biologics, have shown tumor growth inhibition or tumor regression in preclinical models using human tissue transplanted into mice and are currently undergoing clinical evaluation. To date, small molecule receptor tyrosine kinase inhibitors have been hampered by lack of specificity for the cMet target. It has also proven difficult to generate antibodies that are completely inhibitory against the cMet receptor because the antibody structures themselves can lead to pathological activation of the receptors. There are several bivalent antibodies targeting cMet receptors that are undergoing preclinical or early clinical evaluation, but these bivalent antibodies can contribute to this pathological activation, thereby creating a potential safety risk. By contrast, in our *in vitro* studies, PRS-110 inhibits receptor activation and leads to receptor degradation, pointing to its potential to treat tumors linked to the cMet pathway based on what we believe to be its novel mechanism of action.

Pipeline products: 300 Series

Current antibody-based therapies targeting tumor cell destruction or immune activation are hampered by, among other factors, low response rates and the induction of immune-related adverse events. The 300-Series Anticalin® proteins are designed to target checkpoint proteins and consist of a variety of multifunctional biotherapeutics that can combine antibodies with Anticalin proteins. These combined molecules have the potential to build upon current therapies through the capability of modifying or regulating one or more immune functions on a single fusion protein, thereby having the potential to elevate immune responses within a tumor microenvironment. First, the antibody component of this Anticalin protein construct will be able to directly attack tumor cells, causing signal attenuation, tumor debulking and, as a result, antigen presentation. Second, we believe that a tethered Anticalin protein directed at checkpoint proteins can preferentially activate the immune system at the site of the tumor microenvironment. We believe that the 300-Series Anticalin proteins represent a "platform within a product" opportunity in immuno-oncology since it may be possible to apply a single combined Anticalin-antibody molecule in a number of different cancers. This is based on the shared underlying biology such as checkpoint biology found within tumors arising in different organs.

This platform is modular, which we believe will permit rapid evaluation of unique combinations of validated tumor targets and immunomodulatory checkpoint proteins. For example, one panel of 300-Series Anticalin® proteins, currently being evaluated in the preclinical stage of experiments, is directed with specificity and subnanomolar affinity against CTLA4, a protein receptor that downregulates the immune system and which is found on the surface of T cells, regulating T cells at their stage of initial activation, in effect turning "off" the attacking nature of the T cells. In addition, we will test the potential of antagonizing other checkpoint proteins and evaluate the direct activation of immune responses through co-stimulatory molecules, or checkpoint activators. These latter studies are currently in the research phase.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience, scientific knowledge and strategies provide us with competitive advantages, we face and will continue to face intense competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, both in the United States and abroad.

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

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

There are a number of other companies presently working to develop therapies for anemia, asthma and oncology, including divisions of large pharmaceutical companies and biotechnology companies of various sizes. There are also a variety of available drug therapies marketed for these diseases. Our drug candidates, if any are approved, may compete with these existing drug and other therapies, and to the extent they are ultimately used in combination with or as an adjunct to these therapies, our drug candidates may not be competitive with them. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. As a result, market acceptance of, and a significant share of the market for, any of our drug candidates that we successfully introduce to the market will pose challenges.

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

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in some of our competitors. Competition may increase further as a result of advances made in the

commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build, obtain regulatory approval for and market acceptance of, and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

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

- identifying and validating targets;
- screening compounds against targets;
- preclinical and clinical trials of potential pharmaceutical products; and
- obtaining regulatory clearances.

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

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

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

PRS-080

Other drug candidates in development that interfere with hepcidin function or expression include ISIS/Xenon (anti-sense) and Alnylam (RNAi), which have nucleic acid based approaches aimed at reducing hepcidin synthesis in preclinical development. Noxxon's RNA aptamer sequesters hepcidin and is in clinical studies in cancer and ESRD patients. A mAb against hepcidin is tested in cancer as well as chronic kidney disease patients by Lilly as well as a mAb against the ferroportin transporter. Ferrumax develops a soluble form of hemojuvelin, a protein that regulates hepcidin expression and iron metabolism, that aims to suppress the production rate of hepcidin.

There are also a number of companies which are focused on treating anemia in CKD patients under alternative approaches. Fibrogen, Akebia Therapeutics, GSK, Bayer, and Japan Tobacco have hypoxia-inducible-factor prolyl hydroxylase (HIF-PH) inhibitors in clinical development that target stimulation of bone marrow activity. Acceleron is also targeting the sequestration of Activin A, a natural inhibitor of hematopoiesis, is in a Phase II clinical study. Zenerex by Keryx, which targets formulation of oral iron, is currently been tested in Phase II in CKD patients. There are also various companies conducting late-stage development of erythropoietin biosimilars.

PRS-060

Like PRS-060, new developments for the treatment of uncontrolled moderate to severe asthma patients mainly include drug candidates targeting the Th2 pathway by interfering with IL4/IL-13 or IL-5 function. Such products include dupilumab (Sanofi/Regeneron, IL-4RA), lebrikizumab (Roche/Genentech, IL-13), tralokinumab (Astra Zeneca, IL-13), mepolizumab (GSK, IL-5), reslizumab (Teva, IL-5), and benralizumab (Astra Zeneca, IL-5R). These drugs are in later clinical development (Phase II and Phase III) than PRS-060, or were submitted for approval (mepolizumab), however in contrast to PRS-060, these mAbs are given to patients through injection and distribute systemically through the blood stream. There are a number of other companies presently marketing or developing other therapies for asthmatic patients. The mAb omalizumab, directed against IgE, is approved for the treatment of uncontrolled, moderate to severe asthma patients.

PRS-110

Competitor drug candidates targeting the cMet pathway include MetMab (Roche/Genentech), LY2875359 (Eli Lilly), ABT700 (Abbvie) and earlier stage candidates by other companies. MetMab is a monovalent cMet binder, or a one-armed antibody, and has shown efficacy in cMet-high patients (IHC 2+, 3+) in a Phase II trial in non-small-cell lung carcinoma, or NSCLC, patients. However, one Phase III study of MetMab in combination with Erlotinib in NSCLC patients was recently terminated due to lack of a survival benefit, which has led to the decision by Roche to suspend the program. LY2875359 by Eli Lilly and ABT700 by Abbvie are bivalent mAbs against cMet currently in Phase I/II clinical testing. Both mAbs have demonstrated efficacy in Phase I trials.

Several small molecule inhibitors are also undergoing clinical evaluation, including multi-targeted tyrosine kinase inhibitors from ArQule (ARQ197) and Exelixis (XL-184 & XL-880). Crizotinib by Pfizer is an FDA approved small molecule inhibitor, which targets anaplastic lymphoma kinase, or ALK, a protein implicated in certain cancers, and which also has anti-cMet activity. In 2011, Crizotinib was approved for treatment of metastatic NSCLC patients who express ALK fusion proteins. PRS-110 and other cMet-targeting drugs also compete with HGF inhibitors. The monoclonal antibody AMG102 by Amgen is the most advanced HGF-targeting molecule in clinical trials. AV299 by Aveo is another HGF-targeting antibody in clinical development.

PRS-300 series

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

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

Manufacturing

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

We currently rely on one CMO for all of our clinical supplies, including active pharmaceutical ingredients, or APIs, drug substances and finished drug products for our preclinical research and clinical trials, including the Phase I trial for PRS-080.

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

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

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

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

Intellectual Property and Exclusivity

Our commercial success depends in part on our ability to obtain and maintain exclusivity of our proprietary Anticalin®-brand technologies through intellectual property protection for our drug candidates, libraries of different protein scaffolds and consensus sequences and the fundamental Anticalin platform technology, including novel therapeutic and diagnostic discoveries, as well as other proprietary know-how, and to operate without infringing on the intellectual property rights of others.

We seek to protect our exclusive position of Anticalin® technologies by, among other means, prosecuting our own international, U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We established intellectual property protection in relation to our Anticalin technologies in key global markets, including Australia, Brazil, Canada, China, the European Union, Hong Kong, India, Japan, Korea, New Zealand, Russia, Singapore, South Africa and the United States. We believe we have patent exclusivity relating to drug candidates derived from lipocalin proteins that runs until at least 2020 in the U.S. We also rely on trade secrets for confidential know-how, which we generally seek to protect through contractual (e.g. confidentiality) obligations with employees and third parties.

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

We currently, and expect that we will continue to, file patent applications and maintain granted patents directed to our key drug candidates in an effort to establish intellectual property positions relating to new compositions of matter for these drug candidates, as well as novel medical applications of these compounds in the treatment,

prevention or diagnosis of various indications. We also intend to seek patent protection, if available, with respect to biomarkers that may contribute to selecting the right patient population for use of any of our drug candidates, or with respect to pharmaceutical formulations that may be useful to produce final medicinal products.

Following the effective date of our Research and Licensing Agreement with Technische Universität München, or TUM (See "—TUM License Agreement"), and as of March 27, 2015, we owned or were the exclusive licensee of a patent portfolio consisting of several issued U.S. patents, and their respective counterparts in a number of foreign jurisdictions, several pending applications under the Patent Cooperation Treaty, multiple pending U.S. patent applications and corresponding pending patent applications in a number of foreign jurisdictions as well as three pending provisional patent applications, as described in further detail below.

In applicable jurisdictions, we will seek patent term extensions for certain of our patents including the patent term adjustment period in the U.S. If we obtain marketing approval for our drug candidates in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as twelve years of data exclusivity for new biological entities in the United States and as mentioned below, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act, 8 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."

Among the issued patents we own are U.S. patent No. 7,250,297; U.S. patent No. 7,723,476; U.S. patent No. 8,158,753; U.S. patent No. 8,536,307; and their respective counterparts in the European Union, which patents are directed to the basic Anticalin® protein concept and platform technology (i.e. antagonist or agonist compounds derived from a natural lipocalin protein) and are expected to expire in 2018, subject to patent term adjustments in the U.S. of up to 794 days. In addition, we hold issued U.S. patents Nos.: 7,001,882; 7,118,915; 7,691,970; 7,585,940; 7,893,208; and 8,313,924; and their respective counterparts in a number of foreign jurisdictions, which patents are related to libraries of different scaffolds and consensus sequences such as human apolipoprotein D, human neutrophil gelatinase-associated lipocalin, or hNGAL, and human tear lipocalin, and are expected to expire between 2020 and 2027, subject to patent term adjustments in the U.S. of up to 685 days. We also own U.S. patent No. 7,892,827, which is directed to muteins derived from hNGAL having binding specificity for the cytotoxic T lymphocyte-associated antigen, or CTLA-4, and is expected to expire in 2025, subject to a 350-day patent term adjustments in the U.S., and U.S. patent No. 8,313,924, which is directed to muteins of human tear lipocalin having detectable binding affinity to interleukin 4 receptor alpha chain, or IL-4 receptor alpha, and is expected to expire in 2027, subject to a 424 day patent term adjustment in the U.S., as well as their counterparts in the European Union and in a number of foreign jurisdictions.

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

As of March 27, 2015, a significant portion of our pending U.S. patent applications and pending patent applications in foreign jurisdictions was directed to newly-discovered or improved scaffold libraries of lipocalin muteins, compounds derived therefrom, or the uses of such compounds to treat, prevent and mitigate certain diseases and conditions whose pathological development involve the targets of interest as well as to diagnose,

prognose and select treatments for the diseases and conditions. We would expect that any patents that may issue from the pending U.S. patent applications would likely expire between 2029 and 2035 without taking into account possible patent term adjustments or other extensions, however, any and all of these patent applications may not result in issued patents, and not all issued patents may be maintained in force for their entire term. Specifically, granted patents and pending patent applications directed to Anticalin® proteins for the cMet target currently have terms which could expire as late as 2029, and granted patents and pending patent applications directed to Anticalin proteins for each of hepcidin and IL-4RA currently have terms which could expire as late as 2031. We are actively pursuing intellectual property protection for our 300-Series in key global markets that, if granted, could expire as late as 2035. To date, we are not aware of any third party intellectual property for freedom to operate on our platforms or therapeutic programs.

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

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

Strategic Partnerships

Since 2007, Pieris Operating has entered into several licensing, research and development collaborations to complement our drug discovery and early stage development capabilities. Specifically, Pieris Operating has entered into licensing, research and development agreements which are still active as of the date hereof with Allergan, Inc., or Allergan, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA) and collectively, Sanofi, and Daiichi Sankyo. Under these licensing and research and development arrangements, we have developed and conducted or will develop and conduct selection and screening of drug candidates as well as *in vitro* potency and efficacy testing using our Anticalin®-brand drug discovery platform, our Anticalin-brand libraries and other proprietary methods to generate, identify and characterize drug candidates against certain biological targets associated with several diseases. These agreements have provided us with approximately €31 million ($37.5 million) in revenue to date, excluding grant revenues. With respect to discontinued collaborations, we have no ongoing performance obligations, and do not expect to receive any significant additional consideration pursuant to those agreements.

Pieris Operating's agreements with Allergan, Sanofi and Daiichi Sankyo are ongoing and, under which, our partners are obligated to use commercially reasonable efforts to develop and commercialize drug candidates identified in the course of the collaboration. We are entitled to receive from our partners' research, development

and regulatory milestone payments and, in the case of the Sanofi and Daiichi Sankyo collaborations, royalties on net sales for products developed and commercialized under these collaborations. We plan to continue to actively seek out additional collaboration partners.

In addition to Pieris Operating's agreements with Allergan, Sanofi and Daiichi Sankyo, we are partnering with companies with expertise in clinical development, regulatory affairs and biologics manufacturing to advance our pipeline products through clinical trials and to market those products. In 2013, Pieris Operating entered into a co-development alliance with Cadila Healthcare Limited, or Zydus, with respect to the development and sale of certain proprietary products, under which Zydus will focus on developing markets and we will focus on developed markets. Pieris Operating has also entered into a joint development and license agreement with Stelis, establishing a collaboration for clinical development and commercialization of certain of our proprietary products, focusing initially on use in ophthalmological applications.

Certain terms and conditions of our active agreements with Allergan, Sanofi and Daiichi Sankyo are summarized below as well as certain terms and conditions of our co-development agreements with Zydus and Stelis.

Our agreement with Allergan

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

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

The agreement will remain in effect until the expiration of the payment obligations of Allergan to Pieris Operating thereunder. Either party may terminate the agreement in the event of the other party's material breach of the agreement remains uncured for a specified period or in the event the bankruptcy of the other party. Allergan has the unilateral right to terminate the agreement upon specified prior written notice to us. On termination, all rights granted to Allergan in our Anticalin® technologies would end.

Our collaboration with Sanofi

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

In consideration of our obligations, as a part of the collaboration we received a €3.5 million ($4.2 million) upfront payment and specified research funding. We also are entitled to receive payments on the achievement of research, development and commercial milestones for each product, with up to €26.0 million ($31.5 million) in development milestones and up to €18 million ($21.8 million) in commercial milestones for the first therapeutic

application and lesser amounts on subsequent therapeutic applications. We have the ability to receive over €50 million ($60.5 million) potential milestone payments from the active collaboration project, including estimated milestone payments in connection with one or more subsequent applications. Payments due to us also include tiered mid-to mid-high single digit royalties on sales of products. We have agreed that we will not use our Anticalin® technologies to perform, on our own behalf or for third parties, any research or development activities on the same target to which any active program relates. Unless earlier terminated, the agreement will remain in effect until the expiration of all payment and related obligations of Sanofi thereunder.

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

Our collaboration with Daiichi Sankyo

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

We received €7.2 million ($8.7 million) upon signing of the collaboration agreement and received research funding. We are entitled to payment on the achievement of research and development milestones of up to €35.85 million ($43.38 million) for the first prophylactic or therapeutic product, with reduced amounts for achievement of those milestones in additional indications. We are also entitled to payment of commercialization milestones of up to €45 million ($54.5 million) for a prophylactic or therapeutic product. On development and commercialization of a diagnostic product, we are entitled to development and commercialization milestones of up to €675,000 ($816,817). We have the ability to receive up to approximately €200 million ($242 million) in potential milestone payments from the two collaboration projects, including estimated milestone payments in connection with one or more additional indications. Daiichi Sankyo is further obliged to pay to us tiered, mid- to mid-high single digit royalties on sales of products for prophylactic and therapeutic uses and low single digits on sales of products for diagnostic uses. We granted Daiichi Sankyo exclusive license rights worldwide for prophylactic and therapeutic products, and nonexclusive rights for diagnostic uses. During the collaboration, we may not use our Anticalin® technologies in research or commercial activities on the designated targets for our own account or with third parties.

Daiichi Sankyo may terminate any program under the collaboration after a certain research stage for convenience by giving specified prior written notice to us. Either party may also terminate the agreement for a material breach

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

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

Our collaboration with Zydus

In October 2013, Pieris Operating entered into a development and license agreement with Zydus. Under the terms of the agreement, we collaborate with Zydus in the development of certain Anticalin® drug candidates, including PRS-110, and Zydus takes the lead in advancing those products through preclinical and clinical proof of concept development and is responsible for its expenses relating to that advancement, which include drug manufacturing. Zydus has been granted exclusive rights to commercialize these products in India and several other developing countries. We retain the right to commercialize these products in key developed markets. We and Zydus have cross-licensed our respective rights in new inventions derived during the collaboration for these products in these territories.

Under the terms of the collaboration, we would be entitled to a payment on achievement of a certain development milestone in the Zydus territory, and a low-to mid-single digit royalty on product sales. We would also be entitled to a share of Zydus' revenue from a sublicense of its rights in the product. We are obliged on the occurrence of a product's achieving certain development milestones in our territory to make payments to Zydus, and to pay low-single digit royalties on product sales. We also are obliged to share with Zydus a percentage of our revenue received from out-licensing rights in the product in our territory, which percentage varies based on the stage of development of the product at the time of out-licensing, should we choose to out-license the product. Upon completion of a certain stage of clinical development, either party may choose to discontinue development, in which case the other party would have the right to continue development and its payment obligations to the discontinuing party would be reduced. During the term of the agreement, with respect to PRS-110, we may not sell a product, or enable a third party to sell a product, that is the subject of the collaboration in the Zydus territory for use in the treatment, palliation or prevention of certain diseases in humans. Under the terms of the agreement, we could be required to pay up to an aggregate of $18.0 million in milestone payments to Zydus, and could be entitled to a $1.0 million milestone payment from Zydus.

The agreement will remain in effect until both parties cease to have their respective payment obligations thereunder. Either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach, the other party's insolvency, or where the parties conclude that clinical data do not support further development.

Our collaboration with Stelis

In November 2013, Pieris Operating entered into a joint development and license agreement with Stelis. Under the terms of the agreement, we collaborate with Stelis in the development of certain Anticalin® drug candidates, initially for use in the treatment, palliation or prevention of ophthalmology-related diseases. Under the terms of the agreement, we contribute certain proprietary assets to the development project, and Stelis agrees to establish a production process for preclinical and clinical supplies of product at its expense and to perform and fund certain preclinical studies and a first-in-human clinical study for each product under joint development at the expense of Stelis. We agreed that upon reaching certain development stages for a product, we and Stelis would discuss the possible formation of a joint venture with approximately equal shareholding between Pieris Operating and Stelis to further develop and commercialize such product worldwide. If a party does not wish to enter into a joint

venture, the other party may continue development and commercialization of a product, subject to terms and conditions to be established by a separate agreement.

Unless earlier terminated, the agreement will remain in effect on a product by product basis until the later of (i) the parties entry into the joint venture as discussed above, (ii) upon receipt of written notice of a decision not to enter into the joint venture from the other party, the receiving party timely elects to continue development and commercialization of a product, and (iii) the parties agree in good faith on how to dispose of a project in the event that neither party wishes to enter into the joint venture, provided, however, that the term of any product shall automatically end no later than one year after completion of the first phase I trial for such product unless extended by mutual agreement of the parties. Prior to the formation of the joint venture, either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach, or for the other party's insolvency.

TUM License Agreement

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

Under the terms of the agreement TUM 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.

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

As consideration for the assignments and licenses, we are obliged to pay to TUM milestone payments on development of our proprietary products claimed by patents assigned or licensed to us by TUM. For each of such proprietary products developed by us, we could be required to pay up to an aggregate of €175,000 ($211,768) in milestone payments to TUM under the agreement.

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

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

Upon initiation of the Phase I clinical trial of PRS-080 in November 2014, our obligation to pay TUM a milestone payment of €10,000 ($12,101) pursuant to the terms of the TUM License Agreement was triggered. We have certain reporting obligations to TUM under the TUM License Agreement and will report this trigger to TUM pursuant to the terms of the agreement. Upon issuance of such a report, we will be obligated to pay to TUM such milestone payment. We are also currently in a dispute with TUM, which is described in more detail under "Item 3. Legal Proceedings—Arbitration Proceeding with Technische Universität München."

Government Regulation

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process and a new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S. The animal and other non-clinical data and the results of human clinical trials performed under an Investigational New Drug application, or IND, and under similar foreign applications will become part of the NDA.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

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

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An

IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

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

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

The FDA or the sponsor may suspend 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 IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA or BLA is submitted. Meetings at other times may be requested. 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 FDA to reach agreement on the next phase of development. Sponsors typically use the End of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing

process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

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

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an NDA for a new molecular entity and original BLAs will be 6 months from the date that the NDA or BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

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

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted in 2012, made permanent the Pediatric Research Equity Act, or PREA, which requires a sponsor to conduct pediatric studies for

most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for 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, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

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

Biologics Price Competition and Innovation Act of 2009

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics—biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

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

label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

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

In February 2012, the FDA issued 3 draft guidance documents on biosimilar product development. The draft guidance documents are: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product," and "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009." In April 2013, the FDA issued a fourth draft guidance entitled, **"**Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants." The guidance documents provide FDA's current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA received public comments on the draft documents and intends to issue final guidance documents in the future. Nevertheless, the absence of a final guidance document does not prevent a sponsor for seeking licensure of a biosimilar under the BPCIA.

Orphan Drug Designation

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

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

Fast Track Designation and Accelerated Approval

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

Under the fast track program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based

upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

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

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a fast track drug's BLA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. In June 2013, the FDA published a draft Guidance for Industry entitled, "Expedited Programs for Serious Conditions-Drugs and Biologics" which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new drugs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs. In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. FDA has already granted this designation to over 30 new drugs and has approved several.

Post-Approval Requirements

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

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. FDA strictly regulates labeling, advertising, promotion and

other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress 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 changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Foreign Regulation

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

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

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

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, in the EU, if any of our products receive marketing approval in the European Economic Area, or EEA which is comprised of the 28 member states of the EU plus Norway, Iceland and Liechtenstein, we expect they will benefit from 8 years of data exclusivity and an additional 2 years of marketing exclusivity. An additional one-year extension of marketing exclusivity is possible if during the data exclusivity period, we obtain an authorization for one or more new therapeutic indications that is deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product's first marketing authorization in the EU and prevents biosimilars from relying on the holder of the marketing authorization for the reference biological medicine's pharmacological, toxicological and clinical data for a period of 8 years. After 8 years, a biosimilar product application may be submitted and the

sponsoring companies may rely on the marketing authorization holder's data. However, a biosimilar medicine cannot launch until 2 years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or 3 years later (or a total of 11 years after the first marketing authorization in the EU of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the 8 year data exclusivity period.

As in the United States, a sponsor may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

Reimbursement

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

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

Employees

As of March 27, 2015, we had 28 full-time employees and seven part-time employees, including 10 employees with Ph.D. degrees. Of these 35 employees, 29 are engaged in research and development activities and six work in general support and administration. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. 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

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

Item 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes.

Risks Related to Our Business, Financial Position and Capital Requirements

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

We are a clinical-stage biopharmaceutical company. To date, we have not generated any product revenue and are not profitable, and have incurred losses each year since our inception in August 2000. For the years ended December 31, 2014 and 2013 we reported net loss of $9.8 million and net income of $0.1 million, respectively. Our net profit for the year ended December 31, 2013 is not indicative of a trend. As of December 31, 2014 and December 31, 2013, we had an accumulated deficit of $65.8 million and $56.0 million, respectively. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates and the commercialization of approved products, if any.

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

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

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

On December 17, 2014, we closed the Private Placement for gross proceeds to us of $13.56 million. Even after giving effect to the Private Placement, we will require additional capital for the further development and commercialization of our drug candidates and may need to raise additional funds sooner if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we advance PRS-080 through a Phase I clinical trial and prepare for a potential Phase I clinical trial of PRS-060. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to regulatory requirements, product manufacturing, marketing, sales and distribution.

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

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

If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. For instance, in connection with the closings of the Private Placement on December 17, 18 and 23, 2014, we issued an aggregate of 6,779,510 shares of our common stock to investors in that offering as well as Placement Warrants exercisable for an additional 542,360 shares to the Placement Agents and their designees, which together equals approximately 25% of our currently issued and outstanding capital stock.

If we raise additional capital through the incurrence of indebtedness, we would likely become subject to covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

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

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

Our limited operating history as a clinical stage company may hinder our ability to successfully meet our objectives, and may limit the amount of information about us upon which you can base an evaluation of our business and prospects.

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

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

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

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

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

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

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

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

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

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

Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. Our reporting currency is the U.S. dollar and our functional currency is the euro. As such, the financial statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year and (3) stockholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in stockholders' equity.

In 2014, 96.3% of our revenues were generated and 67% of our costs were incurred in euros. As we realize upon our strategy to expand internationally, our exposure to currency risks will increase. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies and the euro will affect our revenues and expenses and could result in exchange losses in any given reporting period.

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

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

Risks Related to the Discovery and Development of Our Drug Candidates

We are heavily dependent on the success of PRS-080 and PRS-060, our early-stage lead drug candidates which are still in clinical and preclinical development, respectively, and we cannot be certain that PRS-080 and PRS-060 will receive regulatory approvals or be successfully commercialized even if we receive regulatory approvals.

We currently have no products that are approved for commercial sale. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead drug candidates, PRS-080 and PRS-060. We initiated a Phase I clinical trial with PRS-080 in healthy volunteers in November 2014 and PRS-060 is in preclinical development. All of our other drug candidates are in the discovery or early preclinical stage. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of PRS-080 and PRS-060, which may never occur.

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

- conduct additional preclinical and clinical development;
- manage preclinical, manufacturing and clinical activities;
- obtain regulatory approval;
- establish manufacturing relationships for the clinical supply of the applicable drug candidate;
- build a commercial sales and marketing team, either internally or by contract with third parties;
- develop and implement marketing strategies; and
- invest significant additional cash in each of the above activities.

If the results of the PRS-080 Phase I clinical trial are not successful, we may not be able to use those results as the basis for advancing the drug candidate into further clinical development. In that case, we may not have the resources to conduct new clinical trials, and/or we may determine that further clinical development of this drug candidate is not justified and may decide to discontinue the program. Clinical testing of PRS-060 has not yet commenced, and the results of any future preclinical studies or clinical trials of PRS-060, if unsuccessful, could lead to our abandonment of the development of that drug candidate as well. If studies of these two drug candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed.

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

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

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

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

If the studies conducted by us or our partners or collaborators have not been in full compliance with applicable regulatory requirements or are otherwise not eligible for continued development in the United States, then we or our partners may be forced to conduct new studies in order to progress the development of our drug candidates. We, or our partners, may not have the funding or other resources to conduct or complete these new studies, which would severely delay the development plans for these drug candidates and their commercialization. Any such deficiency and delay in the development of these drug candidates would significantly harm our business plans, product revenues and prospects.

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

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

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

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

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

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

Although the clinical Phase I trial for PRS-080 in healthy volunteers will be conducted primarily in 2015, and although we are planning to initiate clinical trials for PRS-060 as early as 2016, we may experience delays in pursuing those or any other clinical trials, and any planned clinical trials may not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner, and may not be completed on schedule, if at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Commercialization of Our Drug Candidates

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines or warning letters;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;
- product seizure or detention, or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

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

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

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

- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products;
- the size of the markets for the drug candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the potential and perceived advantages of the drug candidate over alternative treatments;
- the safety of the drug candidate as demonstrated through broad commercial distribution;
- the availability of adequate reimbursement and pricing for our products from governmental health programs and other third-party payors;
- relative convenience and ease of administration;

- cost-effectiveness of our product relative to competing products;
- the prevalence and severity of adverse effects; and
- the effectiveness of sales, marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

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

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

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

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

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

We currently have no sales, marketing or distribution capabilities and there can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any drug candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be

successful in doing so. Therefore, with respect to the commercialization of all or certain of our drug candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products.

If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our drug candidates that receive regulatory approval or any such commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

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

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

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

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

There are several third party drug candidates that could be competitive with drug candidates in our pipeline. Drug candidates interfering with hepcidin function and thus competing with PRS-080 are being developed by Noxxon (NOX-H94), Lilly (LY-2787106, LY-2928057), Ferrumax (FMX-8), ISIS/Xenon (XEN701), and Alnylam (ALN-HPN). Drug candidates interfering with Th2 function and thus competing with PRS-060 are being developed by Sanofi/Regeneron (dupilimab), Roche/Genentech (lebrikizumab), Astra-Zeneca (tralokizumab, benralizumab), GSK (mepolizumab) and Teva (reslizumab). Drug candidates targeting cMet and thus competing with PRS-110 are being developed by Roche / Genentech (MetMab), Eli Lilly (LY2875359) and Abbvie (ABT700). Drugs targeting immunomodulatory checkpoint proteins and thus competing with PRS-300 are currently marketed by Bristol Myers Squibb (Yervoy/ipilimumab, Opdivo/nivolumab) and Merck (Keytruda/ pembrolizumab) and drug candidates are developed by Bristol Myers Squibb (Urelumab / anti-CD137; anti-LAG3; Anti-CD40; Lirilumab/ anti-KIR), Roche / Genentech (MPDL3280A/anti-PDL-1; RG7888 /anti-Ox40), Merck Serono (Avelumab / anti-PDL-1) and AstraZeneca (MEDI4736 / anti-PDL-1; MEDI0680 / anti-PD-1; MEDI6469/ Ox-40; tremelimumab/anti-CTLA-4).

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

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

- developing drugs;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- prosecuting and enforcing intellectual property rights;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of or in-license novel compounds that could make our drug candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval, or discovering, developing and commercializing medicines before we do, which would have a material adverse effect on our business and ability to achieve profitability from future sales of our approved drug candidates, if any. For additional information about our competitors, please see "Item 1. Business—Competition."

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

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

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop on our own or with collaborators. We do not currently carry general product liability insurance. We have put in place applicable product liability insurance, covering us as sponsor and the investigators involved in our Phase I clinical trial of PRS-080 in healthy volunteers, in an amount of up to the lesser of €500,000 ($605,050) per enrolled subject or €10 million ($12.1 million) for the Phase I clinical trial in its entirety. In the future, we will seek to obtain similar insurance coverage with respect to any future clinical trials of our other drug candidates, such as PRS-060, but we may not be able to obtain the levels of coverage desired on acceptable terms, or at all. If we do secure product liability insurance, we may subsequently determine that additional amounts of coverage would be desirable at later stages of clinical development of our drug candidates or upon commencing commercialization of any drug candidate that obtains required approvals, but we may not be able to obtain such additional coverage amounts when needed on acceptable terms, or at all. Unless and until we obtain such insurance, we would be solely responsible for any product liability claims relating to our preclinical and clinical development activities. Further, even after any such insurance coverage is obtained, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by any insurance policies we may then have or that is in excess of the limits of our insurance coverage. We would be required to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by any product liability insurance we may obtain, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Managing Any Growth We May Experience

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

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

In addition, our ability to manage our growth effectively will hinge upon our ability to expand, train, manage and motivate our employees. As of March 27, 2015, we had 28 full-time employees and seven 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.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the

disposal of any hazardous materials we use and wastes we produce. The use of these materials in our business could result in contamination or injury, which could cause damage for which we may be responsible but may not have sufficient resources to pay. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with these laws and regulations, which we may not be able to afford.

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

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

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

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

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

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited or eliminated as a result of the Acquisition, the Private Placement or any other ownership change.

We have incurred substantial losses during our history and do not expect to become profitable in the foreseeable future and may never achieve profitability. Our net profit of $0.1 million for the year ended December 31, 2013 is not indicative of a trend. To the extent we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire or forfeit.

Tax losses under German corporate income tax and trade tax may be used to offset taxable income and trade profit attributable to the same taxpayer, or loss holding entity, within the boundaries of German tax law. As of December 31, 2014, Pieris Operating had net operating loss carryforwards of German corporate income tax of $34.2 million and of trade tax of $34.2 million. Under current laws, tax loss carryforwards may only be used to

offset in any relevant later assessment period (calendar year) €1,000,000 ($1,210,100) plus 60% of the exceeding taxable income and trade profit of such period. Also, 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.

Pieris Operating experienced an ownership change as a result of the Acquisition and/or the Private Placement, and as a result have lost some, and may in the future lose some or all, of the unused German corporate income and trade tax losses carryforwards existing or realized at the time of the Acquisition and/or the Private Placement (including carryforwards). Any forfeiture of such tax losses due to the Acquisition and/or the Private Placement, or due to any other such ownership change, could have an adverse effect on our results of operations.

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

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access as well as telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our drug candidates could be delayed.

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

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

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

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

While we currently have no specific plans to acquire any other businesses, 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.

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 agreement with TUM, we could lose license rights that are important to our business and our operations could be materially harmed.

Under the TUM License Agreement, we in-license significant intellectual property related to our Anticalin® platforms from Technische Universität München, or TUM. Under the terms of the agreement, TUM assigns to us certain materials and records resulting from the research. We retain rights to inventions made by our employees, and TUM assigns to us all inventions made under the agreement jointly by our employees and TUM personnel, provided that our employees have made a certain inventive contribution. With respect to all other inventions made in the course of the research, TUM grants to us worldwide exclusive license rights under patents and patent applications claiming such inventions. TUM retains rights to practice these inventions for research and teaching purposes. We bear the costs of filing, prosecution and maintenance of patents assigned or licensed to us under the agreement.

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

We are also currently in a dispute with TUM. On March 20, 2014, Pieris Operating instituted arbitration proceedings, or the TUM Arbitration, against TUM to address issues regarding the calculation of payments due

from Pieris Operating to TUM under the TUM License Agreement. Pursuant to the terms of the TUM License Agreement, the arbitration is proceeding in Munich, Germany and governed by German law, in accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit.

As required by the TUM License Agreement, Pieris Operating provided to TUM its calculation of the Out-License Fee owed by Pieris Operating to TUM for the period beginning on the effective date of the agreement and ending on December 31, 2012, the Dispute Period, in the amount of $0.4 million excluding value-added tax. TUM has asserted that, under the TUM License Agreement, the Out-License Fee due to TUM for the Dispute Period amounts to $3.4 million excluding value-added tax in the aggregate and has threatened to terminate the TUM License Agreement if the Out-License Fee is not paid. We believe that if TUM sought to terminate the license agreement for cause as a result of this dispute, it would potentially face wrongful termination claims for substantial damages if the arbitral tribunal in the TUM Arbitration sides with Pieris in its final decision regarding the proper amount of the Out-License Fee. Pieris Operating instituted the TUM Arbitration to request the arbitration tribunal to hold that Pieris Operating's calculation of the payments owed to TUM is accurate and shall govern all current and future payments due in respect of the Out-License Fee under the TUM License Agreement. Pieris Operating has reserved a liability on its balance sheet in respect of such payment in the amount of €271,000 ($327,937). An adverse ruling in the TUM Arbitration could have a material adverse effect on Pieris Operating's results of operations and financial condition.

In addition to the TUM License Agreement, we may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential drug candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of our license agreement with TUM, or any future license agreement we may enter on which our business or drug candidates are dependent, TUM 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 our license agreement with TUM, our Anticalin® drug therapies. Under the TUM License Agreement, we can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate our rights in patents assigned to us but would terminate our rights to patents licensed to us under the agreement. The loss of the rights licensed to us under our license agreement with TUM, 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 would be harmed.

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

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

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents;

- if and when patents will be issued;
- whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings (e.g. at the United State Patent and Trademark Office, or the USPTO, or the European Patent Office, or the EPO) in connection with patent rights, which may be costly whether we win or lose.

As a result, the patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may successfully issue 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 infringe the claims made in 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 and defending 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. Although we require all of our employees and certain consultants and advisors to assign inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially adversely affect our market position and business and operational results.

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

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

There may be third-party patents of which we are currently unaware with claims that cover the use or manufacture of our drug candidates. 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 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 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 because they have 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.

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

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

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

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

We have entered into agreements with a number of commercial partners, including university partners, which cover intellectual property. We have, in some cases individually and in other cases along with our partners, filed for patent protection for a number of technologies developed under these agreements and may in the future file for further intellectual property protection and/or seek to commercialize such technologies. Under some of these

agreements, certain intellectual property developed by us and the relevant partner may be subject to joint ownership by us and the partner and our commercial use of such intellectual property may be restricted, or may require written consent from, or a separate agreement with, the partner. In other cases, we may not have any rights to use intellectual property solely developed and owned by the partner. If we cannot obtain commercial use rights for such jointly-owned intellectual property or partner-owned intellectual property, our future product development and commercialization plans may be adversely affected.

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

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

If we pursue any infringement proceeding, a court may decide that a patent of ours or 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 the ability of our drug candidates to compete in those jurisdictions.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Employees

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

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified personnel. We are highly dependent on our management, scientific and medical personnel, especially Stephen S. Yoder, our Chief Executive Officer and President, whose services are critical to the successful implementation of our drug candidate development, our business development and partnerships, and our regulatory and commercialization strategies. Further, as our approach is built in part 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. As of March 27, 2015, we had 35 employees, and we may in the future hire additional employees for research and development or general and administrative activities.

We are not aware of any present intention of any of our executive officers or other members of our senior management team to leave our Company, but our industry tends to experience a high rate of turnover of management personnel and our employees are generally able to terminate their relationships with us on short notice. Pursuant to German employment law, our employment arrangements with employees of Pieris Operating are governed by employment contracts which provide certain defined terms for either party to terminate the employment relationship. Additionally, some members of our team, including our Acting Chief Financial Officer Darlene Deptula-Hicks, are consultants rather than employees, and could terminate their consulting relationship with us at any time or with short notice, depending on the terms of their respective consulting agreements with us.

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

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

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

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

In contrast, in Germany, there is no analogous doctrine of "employment at will". By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. With respect to Pieris Operating, relations between German employers and employees are extensively regulated under German labor and employment laws and regulations. German employees enjoy, in particular, 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* (German Termination Protection Act) and is intended to give the employee maximum protection against unfair dismissal, including among other things:

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

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

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

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, through contractual provisions and other procedures, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employers. Litigation may be necessary to defend against any such claims.

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, provide accurate information to the FDA or EMA, comply with manufacturing standards we have established, comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, report

financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions and procedures we currently take or may establish in the future as our operations and employee base expand to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure by our employees to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to the Ownership of our Common Stock

There is not now, and there may never be, an active, liquid and orderly trading market for our common stock, which may make it difficult for stockholders to sell their shares of our common stock.

Our common stock quoted on the OTC Markets OTCQB tier, or OTCQB, of OTC Markets Group Inc., an over-the-counter quotation system, and there is not now, nor has there been since our inception, any significant trading activity in our common stock or a market for shares of our common stock, and an active trading market for our shares may never develop or be sustained. As a result, investors in our common stock must bear the economic risk of holding those shares for an indefinite period of time. We do not now, and may not in the future, meet the initial listing standards of any national securities exchange, and our common stock may be quoted on the OTCQB or another over-the-counter quotation system for the foreseeable future. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our common stock, and may find few buyers to purchase their stock and few market makers to support its price. As a result of these and other factors, stockholders may be unable to resell their shares of our common stock at or above the price for which they purchased them, at or near quoted bid prices, or at all. Further, an inactive market may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

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

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

- the drug candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those drug candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our drug candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our drug candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our drug candidates, including without limitation clinical trial requirements for approvals;

- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our drug candidates;
- our dependence on third parties, including CROs as well as our current and potential partners that produce companion diagnostic products;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

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

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (i) that a broker or dealer approve a person's account for transactions in penny stocks in accordance with the provisions of Rule 15g-9; and (ii) the

broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased, provided that any such purchase shall not be effected less than two business days after the broker or dealer sends such written agreement to the investor.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (i) obtain financial information, investment experience and investment objectives of the person and (ii) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be reasonably expected to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which: (i) sets forth the basis on which the broker or dealer made the suitability determination; and (ii) in highlight form, confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result, it may be more difficult to execute trades of our common stock which may have an adverse effect on the liquidity of our common stock and your investment.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

The Financial Industry Regulatory Authority, or FINRA, has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. These FINRA requirements may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

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

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

We may have material liabilities that were not discovered before, and have not been discovered since, the closing of the Acquisition.

As a result of the Acquisition, the former business plan and management of Pieris, previously known as Marika Inc., have been abandoned and replaced with the business and management team of Pieris Operating. Prior to the Acquisition, there were no relationships or other connections among the businesses or individuals associated with those two entities. As a result, Pieris may have material liabilities based on activities before the Acquisition that have not been discovered or asserted. We could experience losses as a result of any such undisclosed liabilities that are discovered in the future, which could materially harm our business and financial condition. Although the acquisition agreement entered into in connection with the Acquisition contains customary representations and warranties from Pieris concerning its assets, liabilities, financial condition and affairs, there may be limited or no recourse against Pieris' pre-Acquisition stockholders or principals in the event those representations prove to be untrue. As a result, our current and future stockholders will bear some, or all, of the risks relating to any such unknown or undisclosed liabilities.

We may be exposed to additional risks as a result of "going public" by means of a reverse acquisition transaction.

We may be exposed to additional risks because the business of Pieris Operating has become a public company through a "reverse acquisition" transaction. There has been increased focus by government agencies on transactions such as the Acquisition in recent years, and we may be subject to increased scrutiny by the SEC and other government agencies and holders of our securities as a result of the completion of that transaction. Further, as a result of our existence as a "shell company" under applicable rules of the SEC prior to the closing of the Acquisition on December 17, 2014, we are subject to certain restrictions and limitations for certain specified periods of time relating to potential future issuances of our securities and compliance with applicable SEC rules and regulations. Additionally, our "going public" by means of a reverse acquisition transaction may make it more difficult for us to obtain coverage from securities analysts of major brokerage firms following the Acquisition because there may be little incentive to those brokerage firms to recommend the purchase of our common stock. Further, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an initial public offering, or IPO, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock. The occurrence of any such event could cause our business or stock price to suffer.

If we continue to fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors. However, as discussed in detail below, as an emerging growth company, we are not required to obtain an auditor attestation. As a private company, Pieris Operating was not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the Acquisition. Our management team and Board of Directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, issuers that qualify as "emerging growth companies" under the JOBS Act will not be required to provide an auditor's attestation report on internal

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

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

We do not have sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary or adequate accounting policies, processes and procedures, particularly in the areas of revenue recognition, equity related transactions and other complex, judgmental areas for U.S. GAAP financial reporting and SEC reporting purposes and consequently, we must rely on third party consultants. As disclosed in "Item 9A. Controls and Procedures," these deficiencies represent a material weakness (as defined under the Exchange Act) in our internal control over financial reporting in both design and operation. We may identify additional material weaknesses in the future. Under the Exchange Act, a material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. We are currently developing a plan to design, review, implement and refine internal control over financial reporting and we have retained the services of Darlene Deptula-Hicks, as our Acting Chief Financial Officer, to help us with this process. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls. As permitted by Section 215.02 of the SEC's Compliance and Disclosure Interpretations, management is excluding its assessment of internal controls over financial reporting for the year ended December 31, 2014, which is the year the Acquisition was completed, and we do not expect to have to include such assessment until the year ended December 31, 2015. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

We are not subject to compliance with rules requiring the adoption of certain corporate governance measures and as a result our stockholders have limited protections against interested director transactions, conflicts of interest and similar matters.

The Sarbanes-Oxley Act, as well as rule changes enacted by the SEC, the New York Stock Exchange and the NASDAQ Stock Market as a result of the Sarbanes-Oxley Act, require the implementation of various measures relating to corporate governance. These measures are designed to enhance the integrity of corporate management and the securities markets and apply to securities which are listed on those exchanges. Because we are not presently required to comply with many of the corporate governance provisions we have not yet adopted certain of these measures. Until we comply with such corporate governance measures, regardless of whether such compliance is required, the absence of such standards of corporate governance may leave our stockholders without protections against interested director transactions, conflicts of interest and similar matters.

We do not have a class of our securities registered under Section 12 of the Exchange Act. Until we do or we become subject to Section 15(d) of the Exchange Act, we will be a "voluntary filer."

We are not currently required under Section 13 or Section 15(d) of the Exchange Act to file periodic reports with the SEC. We have in the past voluntarily elected to file some or all of these reports to ensure that sufficient information about us and our operations is publicly available to our stockholders and potential investors. Until we become subject to the reporting requirements under the Exchange Act, we are a "voluntary filer" and we are currently considered a non-reporting issuer under the Exchange Act. We will not be required to file reports under Section 13(a) or 15(d) of the Exchange Act until the earlier to occur of (i) our registration of a class of securities under Section 12 of the Exchange Act, which would be required if we list a class of securities on a national securities exchange or if we meet the size requirements set forth in Section 12(g) of the Exchange Act, or which we may voluntarily elect to undertake at an earlier date, or (ii) the effectiveness of a registration statement under the Securities Act relating to our common stock. We currently anticipate that we will become subject to the reporting requirements under Section 15(d) of the Exchange Act upon the effectiveness of a registration statement under the Securities Act. We also anticipate that we will voluntarily elect to register our common stock under Section 12 of the Exchange Act at which time we would become subject to the reporting requirements under Section 13(a) under the Exchange Act. Until we become subject to the reporting requirements under either Section 13(a) or 15(d) of the Exchange Act, we are not subject to the SEC's proxy rules, and large holders of our capital stock will not be subject to beneficial ownership reporting requirements under Sections 13 or 16 of the Exchange Act and their related rules. As a result, our stockholders and potential investors may not have available to them as much or as robust information as they may have if and when we become subject to those requirements. In addition, if we do not register under Section 12 of the Exchange Act, and remain a "voluntary filer", we could cease filing annual, quarterly or current reports under the Exchange Act.

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

Prior to the closing of the Acquisition, we were deemed a "shell company" under applicable SEC rules and regulations because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted (i) until at least 12 months have elapsed from December 18, 2014, the date on which our Current Report on Form 8-K reflecting our status as a non-shell company, was filed with the SEC and (ii) unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Form 8-K reports. We are currently a "voluntary filer" and upon our becoming subject to the reporting rules under the Exchange Act, we will be subject to the reporting requirements under the Exchange Act. Therefore, unless we register our shares of common stock for sale under the Securities Act, most of our stockholders will be forced to hold their shares of our common stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period, sales may not be made under Rule 144 unless we and any such selling stockholders are in compliance with other requirements of Rule 144. Further, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant time and cash resources. 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 (although none are currently planned). 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 authorizes 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. Upon the closings of the Private Placement on December 17, 18 and 23, 2014, we issued an aggregate of 6,779,510 shares of our common stock and in connection with the Private Placement, we issued 542,360 shares of common stock issuable upon exercise of common stock purchase warrants issued to the Placement Agents and their designees, which equals approximately 25% of our currently issued and outstanding capital stock. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Additionally, issuances of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock, and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders. Furthermore, the Securities Purchase Agreement contains certain anti-dilution provisions. Those anti-dilution provisions provide that, subject in certain exceptions, if we issue and sell equity securities or equity-linked or related securities at a purchase price per share of lower than $2.00 within the 180-day period following December 17, 2014, each Investor in the Private Placement shall be entitled to receive such number of additional shares of our common stock as they would have received had such lower purchase price per share been applicable in the Private Placement, which could result in additional dilution and cause the market price of our securities to decline.

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 after the contractual restrictions on resale of such common stock discussed in this Annual Report lapse, or after those shares become registered for resale pursuant to an effective registration statement, the trading price of our common stock could decline. As of March 27, 2015, a total of 29,270,522 shares of our common stock were outstanding. Of those shares, only 2,500,012 are currently freely tradable, without restriction, in the public market. We have agreed to file one or more registration agreements to register for resale under the Securities Act 6,779,510 shares of common stock, which we issued and sold in the Private Placement, 20,000,000 shares of our common stock, which we issued to former stockholders of Pieris Operating in connection with the closing of the Acquisition, and 542,360 shares of common stock issuable to holders of the Placement Warrants pursuant to the Securities Purchase Agreement. Such shares represent approximately 93% of the outstanding shares of common stock as of March 27, 2015. Upon the effectiveness of any such registration statement, or other registration statement we could elect to file with respect to any other outstanding shares of common stock, 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. As of the date of effectiveness of such registration statement, such shares registered for resale will be freely tradable without restriction, except for the 20,000,000 shares of our common stock that we issued to former stockholders of Pieris Operating in connection with the closing of the Acquisition, which will become freely tradable upon the expiration of certain lock-up restrictions applicable to those shares, which prohibit their sale, disposition or other transfer for a period of six months following December 17, 2014; however, in the case of certain former shareholders of Pieris Operating, the lock-up restrictions prohibit the sale, disposition or other transfer of approximately 80% of such shareholder’s shares.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 701 under the Securities Act, and any future registration of such shares under the Securities Act. 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.

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 Private Placement, we expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of 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 the 2014 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 3,200,000 shares of our common stock and, as of March 27, 2015, we have granted options to purchase 2,519,500 shares of our common stock. The Pieris Plan also includes an "evergreen" provision which provides that the number of shares of our common stock reserved for issuance under the Pieris Plan shall be automatically increased on January 1 of each of year commencing in fiscal 2016 by the lesser of (i) 1,000,000 shares, (ii) 4% of the number shares of our common stock outstanding on such date, and (iii) such other amount determined by the Board of Directors. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

These provisions provide, among other things:

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

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

Our Amended and Restated Articles of Incorporation designate 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 NRS or any provision of the corporation's 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 lawsuits against us and our directors, officers, employees and agents. While there is no Nevada case law addressing the enforceability of this type of provision, Nevada courts have on prior occasion found persuasive authority in Delaware case law in the absence of Nevada statutory or case law specifically addressing an issue of corporate law. The Court of Chancery of the State of Delaware has 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 and our Amended and Restated Bylaws eliminate to the furthest extent permitted under Nevada law the personal liability of our directors and officers to us, our stockholders and creditors for damages as a result of any act or failure to act in his or her capacity as a director or officer. Further, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and individual indemnification agreements that we have entered with each of our directors and officers provide that we are obligated to indemnify, subject to certain exceptions, each of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, to advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for such damages, even if such actions might otherwise benefit our stockholders.

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

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

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

As a public company, and particularly if and after we cease to be a an "emerging growth company" or a "smaller reporting company," we will incur significant legal, accounting and other expenses that Pieris Operating did not incur as a private company including costs associated with public company reporting requirements. In addition, the rules and regulations of the SEC and any national securities exchange to which we may be subject in the future impose numerous requirements on public companies, including requirements relating to our corporate governance practices and requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, with which we will now need to comply. We have incurred and expect to continue to incur substantial expenses in connection with the preparation and filing of a registration statement required by our Registration Rights Agreement and expect to incur additional expenses in connection with responding to SEC comments in connection with its review of such registration statement. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We are unable currently to estimate these costs with any degree of certainty.

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

We are an emerging growth company under the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board. If we do, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

We rent approximately 1,414 square meters of office and laboratory space in Freising, Germany under a lease that provides for a monthly rent payment of €18,200 ($22,024), or €218,400 ($264,286) annually. This lease may be terminated by either party subject to an 8-month notice period, provided, however, that such period must finish at the end of a quarter and, if not, the notice period will be extended to the following quarter-end. We believe that our facilities are sufficient to meet our current needs and we will look for suitable additional space as and when needed.

Item 3. LEGAL PROCEEDINGS

Arbitration Proceeding with Technische Universität München

On March 20, 2014, Pieris Operating instituted arbitration proceedings, or the TUM Arbitration, against Technische Universität München, or Munich Technical University and hereafter TUM, to address issues regarding the calculation of payments due from Pieris Operating to TUM under Pieris Operating's Research and Licensing Agreement with TUM, as amended, or the TUM License Agreement. Pursuant to the terms of the TUM License Agreement, the arbitration is proceeding in Munich, Germany and governed by German law, in accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit.

On July 4, 2003, or the Effective Date, Pieris Operating and TUM entered into the TUM License Agreement, as superseded and replaced on July 26, 2007, under which TUM has exclusively licensed, or in some cases assigned, to Pieris Operating certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, Pieris Operating agreed to pay to TUM certain undisclosed annual license

fees, milestones and royalties for its own proprietary drug development and sales, as well as an undisclosed variable fee as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fees are creditable against annual license payments to TUM.

As required by the TUM License Agreement, Pieris Operating provided to TUM its calculation of the Out-License Fee owed by Pieris Operating to TUM for the period beginning on the Effective Date and ending on December 31, 2012, the Dispute Period, in the amount of $0.4 million excluding value-added tax. TUM has asserted that, under the TUM License Agreement, the Out-License Fee due to TUM for the Dispute Period amounts to $3.4 million excluding value-added tax in the aggregate and has threatened to terminate the TUM License Agreement if the Out-License Fee is not paid. We believe that if TUM sought to terminate the license agreement for cause as a result of this dispute, it would potentially face wrongful termination claims for substantial damages if the arbitral tribunal in the TUM Arbitration sides with Pieris in its final decision regarding the proper amount of the Out-License Fee. Pieris Operating instituted the TUM Arbitration to request the arbitration tribunal to hold that Pieris Operating's calculation of the payments owed to TUM is accurate and shall govern all current and future payments due in respect of the Out-License Fee under the TUM License Agreement. Pieris Operating has reserved a liability on its balance sheet in respect of such payment in the amount of €271,000 ($327,937). An adverse ruling in the TUM Arbitration could have a material adverse effect on Pieris Operating's results of operations and financial condition.

In April 2014, TUM argued to the arbitrators that it is not the proper party to be sued under the action for a declaratory arbitration decision brought by Pieris Operating in relation to the Research and Licensing Agreement, and that instead, it is the Free State of Bavaria that is the proper respondent to the action. Pieris Operating has responded that TUM has capacity to be sued in relation to any disputes arising from and regarding contractual provisions of the Research and Licensing Agreement and is thus also the proper respondent in the action. In accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit, each party to the arbitration proceeding has appointed one arbitrator and the party-named arbitrators collectively selected the third arbitrator as the chairman of the arbitration panel.

On December 1, 2014, TUM filed its statement of defense, maintaining its earlier calculation of the Out-License Fee. On December 23, 2014, TUM filed a counterclaim in the amount of €2,529,400 ($3,060,827) to suspend the statute of limitations on its claims. On January 12, 2015, Pieris Operating filed a reply brief in response to TUM's defense.

The arbitration panel held its first hearing in Munich, Germany on January 20, 2015, however the arbitration panel did not come to a conclusion on whether TUM is the proper respondent in the action or on the merits of the case. The panel had previously indicated that it will first decide the issue of whether TUM is the proper respondent in this action. The panel resolved that the value in dispute for both parties' claims and counterclaims would be fixed at €3,500,000 ($4,235,350), as the calculation of the outstanding Out-Licensing Fee also impacts future payments. On March 3, 2015, Pieris Operating submitted a reply brief responding to TUM's statement of defense and counterclaim. TUM must submit a rebuttal brief by March 31, 2015.

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is quoted on the OTC Markets OTCQB tier, or OTCQB, of OTC Markets Group, Inc. under the symbol "PIRS." As of March 26, 2015, the closing bid price for our common stock as reported on the OTCQB was $3.20 per share. Our common stock commenced public trading on January 28, 2014 on the OTC Markets, OTCPink (Current Information) tier of the OTC Markets Group, Inc. Although our common stock is quoted on the OTCQB, there is a limited trading market for our common stock and there have been few trades in our common stock to date. Because our common stock is thinly traded, any reported sale prices may not be a true market-based valuation of our common stock. The following table sets forth, for the periods indicated, the high and low closing bid quotations for our common stock, as reported by OTCQB, since the common stock commenced public trading:

	Common Stock	
	High	Low
2014:		
First Quarter	(1)	(1)
Second Quarter	(1)	(1)
Third Quarter	(1)	(1)
Fourth Quarter	$2.60	$0.01

(1) There was no market for our common stock during this period

Source:
OTCMarkets

Stockholders

As of March 27, 2015, there were 166 stockholders of record of our common stock.

Dividends

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

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. SELECTED FINANCIAL DATA

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 biopharmaceutical company dedicated to the discovery and development of our Anticalin® class of biotherapeutics for patients with diseases in which we believe there is high unmet medical need. Our current development plans focus mainly on two drug candidates, PRS-080 and PRS-060. PRS-080 is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. PRS-080 has been designed to target hepcidin for the treatment of functional iron deficiency, or FID, in anemic patients with chronic kidney disease, or CKD, particularly in end-stage renal disease patients requiring dialysis. PRS-060 is a drug candidate that binds to the IL-4RA receptor, thereby inhibiting IL-4 and IL-13, two cytokines, small proteins mediating signaling between cells within the human body, known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases. We initiated a Phase I clinical trial with PRS-080 in healthy volunteers in November 2014. The trial is currently enrolling subjects and we expect to report the data from this trial by the end of 2015. PRS-060 is currently in preclinical development, and we intend to begin a Phase I clinical trial with PRS-060 in 2016.

We are also developing PRS-110 and our 300-Series Anticalin® proteins in oncology. PRS-110 is a monovalent antagonist, a polypeptide molecule with one target-binding domain, that is designed to block both ligand-dependent and ligand-independent activity. cMet is a receptor tyrosine kinase, a well-known high-affinity cell surface receptor that transmits signals into the cell when a corresponding ligand binds to it, which is essential for embryonic development and wound healing and has been associated with several different cancers, including renal, gastric and lung carcinomas, central nervous system tumors and sarcomas. Our second set of oncology drug candidates is our 300-Series "platform within a product" opportunity in immuno-oncology. The 300-Series Anticalin proteins target checkpoint proteins and define a variety of multifunctional biotherapeutics that genetically link an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein. We are conducting preclinical experiments on a number of 300-Series lead candidates and intend to choose a candidate for clinical trials in oncology by the end of 2015.

Our core Anticalin® technology and platform was developed in Germany, and we have partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India. These include existing agreements with Daiichi Sankyo Company Limited, or Daiichi Sankyo, and Sanofi Group, or Sanofi, pursuant to which our Anticalin platform has consistently achieved its development milestones. We have discovery and preclinical collaboration and service agreements with both academic institutions and private firms in Australia. We also intend to establish a greater U.S. presence and take advantage of the U.S. capital markets, additional potential corporate partners, and the broad expertise found in the biotechnology industry in the United States.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. For the years ended December 31, 2014 and 2013, we reported net loss of $9.8 million and net income of $0.1 million, respectively. As of December 31, 2014, we had an accumulated deficit of $65.8 million. Our net profit for the year ended December 31, 2013 is not

indicative of a trend. 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 at least the next several years. Our revenues for the fiscal years ended December 31, 2014 and 2013 were primarily from license and collaboration agreements with our partners, and, to a lesser extent, from grants from government agencies.

The U.S. dollar is the reporting currency for all periods presented. The functional currency for Pieris Operating is euros. All assets and liabilities denominated in euros are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the average rate during the period. Equity transactions are translated using historical exchange rates. Adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive loss. Pieris is a holding company without operations and the sole stockholder of Pieris Operating. The corporate headquarters and research facility of Pieris Operating are located in Freising, Germany. Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris Operating, was formed on February 14, 2014 to conduct research and development in Australia. Pieris Australia Pty Ltd. has entered into preclinical service agreements with certain service providers in Australia and such service providers have performed some of the services required under the respective agreements.

Private Placement

On December 17, 2014, we entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain accredited investors providing for the issuance and sale to such investors of an aggregate of 6,779,510 shares of our common stock in a private placement which closed in a series of closings on December 17, 18 and 23, 2014, or the Private Placement. All shares issued in the Private Placement were sold at a purchase price per share of $2.00, for aggregate gross proceeds of $13.56 million. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.04 million. Furthermore, the Securities Purchase Agreement contains certain anti-dilution provisions. Those anti-dilution provisions provide that, subject to certain exceptions, if we issue and sell equity securities or equity-linked or related securities at a purchase price per share of lower than $2.00 within the 180-day period following December 17, 2014, each Investor in the Private Placement shall be entitled to receive such number of additional shares of our common stock as they would have received had such lower purchase price per share been applicable in the Private Placement. In connection with the Private Placement, we entered into a registration rights agreement, or the Registration Rights Agreement, with the investors that participated in the Private Placement, pursuant to which we agreed to file with the SEC, the Registration Statement relating to the resale of the shares of our common stock issued and sold in the Private Placement as well the shares of the Company's common stock issued to the former stockholders of Pieris Operating, which such shareholders received in connection Acquisition, as defined below, and shares of the Company's common stock issuable upon exercise of the common stock warrants issued to the Placement Agents and their designees.

Acquisition

On December 17, 2014, Pieris, Pieris Operating and the former stockholders of Pieris Operating entered into an Acquisition Agreement, or the Acquisition Agreement, and completed the Acquisition, pursuant to which the stockholders of Pieris Operating contributed all of their equity interests in Pieris Operating to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris Operating becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. On December 5, 2014, Pieris completed a 2.272727-for-1 forward split of its common stock in the form of a share dividend, with the result that 6,100,000 shares of common stock outstanding immediately prior to the stock split became 13,863,647 shares of common stock outstanding

immediately thereafter. On December 16, 2014, prior to the closing of the Acquisition, Pieris amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to "Pieris Pharmaceuticals, Inc.," and increase its authorized capital stock from 75,000,000 shares of common stock, par value $0.001 per share, to 300,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value $0.001 per share. On December 17, 2014, Pieris transferred its pre-Acquisition assets and liabilities to its former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris common stock. All share and per share numbers in this Annual Report on Form 10-K relating to our shares of common stock have been adjusted to give effect to the stock split described above, unless otherwise stated.

At the closing of the Acquisition, Pieris issued an aggregate of 20,000,000 shares of its common stock to the former stockholders of Pieris Operating in exchange for all of the outstanding shares (common and preferred) of Pieris Operating's capital stock. Pieris Operating became a wholly owned subsidiary of Pieris, and the former stockholders of Pieris Operating collectively own approximately 68.3% of the outstanding shares of Pieris' common stock.

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, section 805 entitled, "*Business Combinations*," Pieris Operating is considered the accounting acquirer in the Acquisition and will account for the transaction as a capital transaction. Consequently, the assets and liabilities and the historical operations that will be reflected in our financial statements will be those of Pieris Operating and will be recorded at the historical cost basis of Pieris Operating.

TUM Arbitration

On March 20, 2014, Pieris Operating instituted arbitration proceedings, against TUM, to address issues regarding the calculation of payments due from Pieris Operating to TUM under Pieris Operating's Research and Licensing Agreement with TUM, as amended. Under the agreement, TUM has exclusively licensed, or in some cases assigned, to Pieris Operating certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, Pieris Operating agreed to pay to TUM certain annual license fees, milestones and royalties for its own proprietary drug development and sales, as well as a variable fee as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fee is creditable against annual license payments to TUM. As required by the agreement, Pieris Operating provided to TUM its calculation of the Out-License Fee for the period beginning July 4, 2003 and ending on December 31, 2012 in the amount of $0.4 million excluding value-added tax. TUM has asserted that the Out-License Fee for this period amounts to €2.5 million ($3.0 million) excluding value-added tax and has threatened to terminate the license agreement if the Out-License Fee is not paid. We believe that if TUM sought to terminate the license agreement for cause as a result of this dispute, it would potentially face wrongful termination claims for substantial damages if the arbitral tribunal in the TUM Arbitration sides with Pieris in its final decision regarding the proper amount of the Out-License Fee. Pieris Operating instituted arbitration to request confirmation that Pieris Operating's calculation of the payments owed to TUM is accurate and will govern all current and future payments due in respect of the Out-License Fee under the agreement.

In April 2014, TUM argued to the arbitrators that it is not the proper party to be sued under the action for a declaratory arbitration decision brought by Pieris Operating in relation to the agreement, and that instead, it is the Free State of Bavaria that is the proper respondent to the action. Pieris Operating has responded that TUM has capacity to be sued in relation to any disputes arising from and regarding contractual provisions of the agreement and is thus also the proper respondent in the action. In accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit, each party to the arbitration proceeding has appointed one arbitrator and the party-named arbitrators collectively selected the third arbitrator as the chairman of the arbitration panel. Pieris operating has recorded a liability on its balance sheet in respect of such payment in the amount of €271,000 ($327,937).

On December 1, 2014, TUM filed its statement of defense, maintaining its earlier calculation of the Out-License Fee. On December 23, 2014, TUM filed a counterclaim in the amount of €2,529,400 ($3,060,827) to suspend the statute of limitations on its claims.

On January 12, 2015, Pieris Operating filed a reply brief in response to TUM's statement of defense, filed on December 1, 2014. The arbitration panel held its first hearing in Munich, Germany on January 20, 2015, however the arbitration panel did not come to a conclusion on whether TUM is the proper respondent in the action or on the merits of the case. The panel had previously indicated that it will first decide the issue of whether TUM is the proper respondent in this action. The panel resolved that the value in dispute for both parties' claims and counterclaims would be fixed at €3,500,000 ($4,235,350), as the calculation of the outstanding Out-Licensing Fee also impacts future payments. On March 3, 2015, Pieris Operating submitted a reply brief responding to TUM's statement of defense and counterclaim. TUM must submit a rebuttal brief by March 31, 2015.

For more information about the TUM arbitration, see "Item 3. Legal Proceedings—Arbitration Proceeding with Technische Universität München."

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 at least the next several years. Our revenues for the last two years have been primarily from the license and collaboration agreements with Sanofi Group, or Sanofi, and Daiichi Sankyo Company Limited, or Daiichi Sankyo and, to a much lesser extent, grants from government agencies.

The revenues from Sanofi and Daiichi Sankyo have been comprised primarily of upfront payments, research and development services and, to a lesser extent, milestone payments. We recognized revenues from upfront payments under these agreements on a straight-line basis over the required service period because we determined that the licenses to which the payments related did not have standalone value. Research service revenue is recognized when the costs are incurred and the services have been performed. Revenue from milestone payments is recognized when all of the following conditions are met: (1) the milestone payments are non-refundable, (2) the achievement of the milestone involves substantial risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment.

We expect our revenues for the next several years to consist of upfront payments, research funding and milestone payments from strategic collaborations we currently have or may establish in the future. We also may receive grants from government agencies and foundations funds in connection with our drug development efforts.

Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable with any certainty to estimate either the costs or the timelines in which those costs will be incurred. Our current development plans focus on two lead drug candidates: PRS-080 and PRS-060. These programs consume a large proportion of our current, as well as projected, resources. We anticipate that our expenses will increase significantly compared to recent years as we advance PRS-080 through clinical trials, including a Phase I clinical trial in healthy volunteers initiated in

November 2014, engage in first-in-man-enabling preclinical studies for PRS-060 and, subsequently, clinical development activities for this program, and prepare drug supply for these and other product candidates. We also expect to incur expenses associated with:

- further preclinical development activities for 300-Series programs;
- establishing and managing relationships with third parties with respect to collaboration and out-licensing; and
- validating and developing additional novel drug candidates.

Any failure or delay in the advancement of PRS-080 or PRS-060 could require us to re-allocate resources from our other projects to the advancement of those drug candidates, which could have a material adverse impact on the advancement of other projects and on our operations.

Our operating expenses are comprised of research and development expenses and general and administrative expenses. Our research and development costs include costs that are directly attributable to the creation of certain of our Anticalin® drug candidates and are comprised of:

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

General and administrative expenses consist primarily of salaries and benefits for employees in executive, finance, business development, legal, accounting, human resources and other support functions. Other significant general and administrative expenses include the costs associated with obtaining and maintaining our intellectual property portfolio, professional fees for accounting, auditing, consulting and legal services, travel and allocated expenses.

Results of Operations

Comparison of Years Ended December 31, 2014 and December 31, 2013

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2014 and 2013:

	Year Ended December 31, 2014	Year Ended December 31, 2013
	(in thousands)	
Revenues	$ 5,365	$12,427
Research and development expenses	(5,600)	(9,412)
General and administrative expenses	(6,963)	(2,461)
Other income (expense)	(2,652)	(488)
Income tax benefit	0	0
Net profit (loss)	$(9,850)	$ 66

Revenues

The following table provides a comparison of revenues for the years ended December 31, 2014 and 2013 (amounts in thousands):

	Year Ended December 31, 2014	Year Ended December 31, 2013
	(in thousands)	
Upfront payments	$ 473	$ 5,159
Research and development services	877	3,592
Milestone payments	3,185	1,129
Grants	830	2,547
Total	$5,365	$12,427

The decrease in revenues from upfront payments in the fiscal year ended December 31, 2014 compared to the fiscal year ended December 31, 2013 related primarily to the successful hand over to collaboration partners of collaboration projects in June 2014, October 2014 and March 2013, and the termination of one collaboration project in November 2013. Because the recognition of upfront payments is spread over the expected time period in which we are performing research services for corresponding partner projects and until hand-over or termination of the projects, we realized more revenues from upfront payments for collaboration projects in 2013 than in 2014. In 2014, we only realized revenues from upfront payments for two collaboration projects from January to June 2014 and one out of the two collaboration projects from July to October 2014, compared to realized revenues for upfront payments for four collaboration projects from January to March 2013 and three out the four collaboration projects from January to November 2013 in fiscal year ended December 31, 2013.

The $2.7 million decrease in revenues from research and development services in the fiscal year ended December 31, 2014 compared to the fiscal year ended December 31, 2013 related primarily to a $2.1 million decrease in research funding from collaboration partners. In the fiscal year ended December 31, 2013, we received research funding from collaboration partners for four collaboration projects, whereas in the fiscal year end December 31, 2014 we received research funding from collaboration partners for only two collaboration projects. Due to the successful hand over of both of these remaining collaboration projects in 2014 we have not received research funding from collaboration partners since July 2014.

The increase of $2.1 million in revenues from milestone payments is due to the achievement of later-stage, higher value milestones in the fiscal year ended December 31, 2014 compared to the fiscal year ended December 31, 2013. In the fiscal year ended December 31, 2013, we achieved four research milestones under collaboration projects with our collaboration partners whereas in the fiscal year ended December 31, 2014, we achieved three research milestones under collaboration projects with our collaboration partners.

The decrease in revenues from grants in the fiscal year ended December 31, 2014 compared to the fiscal year ended December 31, 2013 related primarily to our significantly decreased activities related to PRS-080's development in 2014 compared to 2013, resulting in lower reimbursement from the European Commission for PRS-080's development.

Research and Development Expenses

Total research and development expenses were $5.6 million for the fiscal year ended December 31, 2014 as compared to $9.4 million for the fiscal year ended December 31, 2013.

The $3.8 million decrease in total research and development expenses in the fiscal year ended December 31, 2014 compared to the fiscal year ended December 31, 2013 is primarily due to decreased external activities associated with PRS-080 in the fiscal year ended December 31, 2014.

Our research and development expenses for advancing our proprietary and co-development projects and improving and maintaining our Anticalin® platform technology were $5.4 million and $8.4 million during the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, we employed 25 full-time and seven part-time personnel in our research and development group compared to 32 full-time and two part-time personnel in our research and development group as of December 31, 2013. We incurred expenses of $0.7 million and $3.3 million during the years ended December 31, 2014 and 2013, respectively, for amounts payable to external parties who performed research and development activities for our proprietary and co-development projects and platform technology.

The following table provides a comparison of the research and development expenses for our drug candidates and projects that are described in detail under "Item 1. Business—Pipeline" for the years ended December 31, 2014 and 2013 (amounts in thousands):

	Year Ended December 31, 2014	Year Ended December 31, 2013
	(in thousands)	
PRS-060	$ 86	$ 39
PRS-080	1,384	4,188
PRS-110	151	268
PRS-300 series	596	0
Total	$2,217	$4,495

In addition to the amounts outlined above, we incurred $3.2 million and $3.9 million in connection with early stage research projects and platform technology development during the years ended December 31, 2014 and 2013, respectively.

We incurred $0.2 million and $1.0 million of costs in relation to providing research and development services under the license and collaboration agreements with our collaboration partners for the years ended December 31, 2014 and 2013, respectively.

General and Administrative Expenses

General and administrative expenses increased from $2.5 million for the year ended December 31, 2013 to $7.0 million in 2014. The increase resulted primarily from the completion of the Acquisition and the Private Placement.

Other Income (Expense)

Other expense increased to $2.7 million in the fiscal year ended December 31, 2014 from $0.5 million for the fiscal year ended December 31, 2013. This increase results from the conversion of the convertible bridge loan we obtained in November 2012 into shares of common stock and relates to the beneficial conversion feature thereto in an amount of $2.2 million. The beneficial conversion feature was a nondetachable conversion feature which was in the money at the conversion date, since its effective exercise price was less than the current fair value of the share.

Liquidity and Capital Resources

Through December 31, 2014, we have funded our operations with $141.2 million of cash that has been obtained from the following main sources: $76.9 million from sales of equity; $6.5 million from loans; $13.8 million from grants from government agencies; and $43.8 million in total payments received under license and collaboration agreements, including $7.9 million for research and development services costs we received in 2012, 2013 and 2014 from Daiichi Sankyo and Sanofi. We expect that reimbursements of our development costs by Daiichi Sankyo and Sanofi will decline going forward, and we do not expect such reimbursements to be a significant source of funding in the future.

As of December 31, 2014, we had a total of $18.5 million in cash and cash equivalents and $3.9 million of liabilities, consisting of $3.5 million of current liabilities from operations. We used $3.5 million and $2.5 million of working capital to fund recurring operations during the years ended December 31, 2013 and December 31, 2014, respectively.

Pieris Operating has experienced operating losses since its inception and had a total accumulated deficit of $65.8 million as of December 31, 2014. Pieris Operating expects to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception and in the year ended December 31, 2014. These losses have resulted in significant cash used in operations. During the fiscal years ended December 31, 2014 and 2013, our cash used in operations was $5.3 million and $3.1 million, respectively. While we have several research and development programs underway, the PRS-080 and PRS-060 programs have advanced the furthest and will continue to consume increasing amounts of cash for conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of PRS-080 and PRS-060 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years.

On December 17, 2014 we entered into a the Securities Purchase Agreement, with the Investors, providing for the issuance and sale to such Investors of an aggregate of 6,779,510 shares of our common stock in the Private Placement for gross proceeds to us of $13.56 million. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.04 million.

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

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

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

We cannot be sure that future funding will be available to us on acceptable terms, or at all. Due to often volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress for our PRS-080 or PRS-060 program 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.

If we cannot raise adequate capital in the future, we will be required to delay and possibly eliminate the research and development work not only of our lead drug candidates PRS-080 and PRS-060, but also our other preclinical stage product candidates. In this case, we could be required to relinquish greater or all rights to our product candidates at an earlier stage of development and on less favorable terms than we would otherwise agree.

Our cash is maintained in money market accounts and, to a lesser extent, in current cash accounts at major financial institutions. Due to the current low interest rates available for these instruments, we are earning limited interest income. Our investment portfolio has not been adversely impacted by the problems in the credit markets that have existed over the last several years, but there can be no assurance that our investment portfolio will not be adversely affected in the future.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

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

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.

Multiple-element arrangements

We enter into licensing and development agreements with collaboration partners for the development of Anticalin® therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include (i) licenses, or options to obtain licenses, to our

Anticalin technology and (ii) research and development activities with respect to one or more therapeutics related to such licenses. Payments to us under these agreements may include upfront fees (which include license and option fees), payments for research and development services, 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 contain material financial consequences to us. We follow the provisions of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

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

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units. We have used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to our proprietary technology because we do not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to our proprietary technology, we consider market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. Significant changes in key assumptions used to determine the best estimate of selling price could have a significant effect on the allocation of arrangement consideration, which could have a material effect on the timing of revenue recognition.

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

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

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

In arrangements where options to obtain additional licenses are considered substantive, we do not consider the additional licenses to be a deliverable at the inception of the agreement. When a collaborator exercises the option to acquire the additional license, the exercise fee is attributed to the additional license, and we apply the multiple-

element revenue recognition criteria to all deliverables in the arrangement, which will be consistent with the treatment of up-front payments for licenses (*i.e.,* license and research and development services). In the event an option expires and is not exercised, any deferred amounts attributable to the optional licenses are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and we apply the multiple-element revenue recognition criteria to determine accounting treatment. None of our agreements has been determined to contain non-substantive options.

Payments or reimbursements resulting from our research and development efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue.

Milestone payments

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

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

Revenues from research and development milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, are recognized entirely upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Government grants

Government grants are recognized when there is reasonable assurance that all conditions will be complied with and the grant will be received. As government grants received by us generally represent subsidies for specified activities, they are recognized when earned as a reduction of the expenses recorded for the activity that the grants are intended to compensate. Thus, revenues from a grant relating to research and development expense are recognized over the same period in which the related costs are incurred.

Loss contingencies

We record accruals for loss contingencies to the extent that we conclude that 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. We consider all claims on a quarterly basis in accordance with GAAP and based on known facts assess whether potential losses are considered reasonably possible, probable and estimable. Based upon this assessment, we then evaluate disclosure requirements and whether to accrue for such claims in our financial statements.

Under the Research and License Agreement between Pieris Operating and Technische Universität München dated as of July 26, 2007, or the TUM License Agreement, Pieris Operating is required make payments to TUM based on the Pieris Operating's revenues generated from entering into sub-licensing agreements with any third party with respect to both University Inventions and Joint Inventions (each as defined in the agreement). These revenues include up-front payments as well as milestone payments received by Pieris Operating from third parties.

As Pieris Operating signed six sub-licensing agreements between 2004 and 2012 under which it has recorded revenues, Pieris Operating acknowledges an obligation to TUM. However, the parties disagree regarding the amount due. Pieris Operating commenced arbitration proceedings to resolve the dispute. Although it is not possible to predict the outcome of such arbitration, the Company has assessed the degree of probability and the potential losses that it could incur as a result of these matters. The Company believes that an accrual for probable liability under the agreement (in an amount of €271,000 ($327,937)) is a reasonable estimate for potential future payment obligations in respect of the period between 2004 and 2012. The estimated losses are based on currently available information and involve elements of judgment and significant uncertainties, and actual losses may differ from the accrual set for any such liabilities under the agreement.

The amount currently in dispute is €3,500,000 ($4,235,350), as described in more detail under "Item 3. Legal Proceedings."

Income taxes

We apply ASC 740—Income Taxes, which established financial accounting and reporting requirements for the effects of income taxes that result from our 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 carryforwards. 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 we determine 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 valuation allowance is sufficient to reduce the deferred tax assets to the amount that we determine is more likely than not to be realized.

Management's evaluation with regard to the probability of realizing its deferred tax assets is that it is more likely than not that we may not realize the benefit of its deferred tax asset. This evaluation is based on our history of operating losses and an actual outlook that we will experience losses in the foreseeable future. The net profit for the year ended December 31, 2013 is not indicative of a trend. Accordingly deferred tax assets have been fully reserved as of December 31, 2013 and 2014.

Recently Issued Accounting Pronouncements

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

Emerging Growth Company and Smaller Reporting Company Status

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

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

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

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date

of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019. We will remain a smaller reporting company until we have a public float of $75 million or more as of the last business day of our most recently completed second fiscal quarter. We also expect that we will remain a smaller reporting company for the foreseeable future, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

Emerging growth companies may elect to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

Voluntary Filer Status

We do not currently have a class of securities registered under Section 12 of the Exchange Act. Additionally, we have not had a registration statement declared effective under the Securities Act during our current fiscal year and, as of the beginning of our current fiscal year, our common stock was held of record by less than 300 persons. As a result, we are not currently required to file reports under Section 13(a) or under Section 15(d) of the Exchange Act and are a considered a "voluntary filer" with respect to the reports we do file under those sections. We will not be required to file reports under Section 13(a) or 15(d) of the Exchange Act until the earlier to occur of (i) our registration of a class of securities under Section 12 of the Exchange Act, which would be required if we list a class of securities on a national securities exchange or if we meet the size requirements set forth in Section 12(g) of the Exchange Act, or which we may voluntarily elect to undertake at an earlier date, or (ii) the effectiveness of a registration statement under the Securities Act relating to our common stock. We expect that we will become subject to the reporting requirements under Section 15(d) of the Exchange Act upon the effectiveness of a registration statement under the Securities Act. We also anticipate that we will voluntarily elect to register our common stock under Section 12 of the Exchange Act at which time we would become subject to the reporting requirements under Section 13(a) under the Exchange Act. Until we become subject to the reporting requirements under either Section 13(a) or 15(d) of the Exchange Act, we expect that we will voluntarily file the reports that we would be required to file if we were subject to those sections.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have

concluded that, based on such evaluation, our disclosure controls and procedures were not effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, due to a material weakness in internal control over financial reporting.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for the appointment of Darlene Deptula-Hicks, our Acting Chief Financial Officer.

Management's Assessment of Internal Control over Financial Reporting

The management of the company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended.

Pieris Operating has historically been a private company and did not maintain the internal accounting and financial reporting resources necessary to comply with the obligations of a public reporting company, including maintaining effective internal controls over financial reporting. The internal controls of the legal acquirer, a non-operating shell company did not exist as of the Acquisition date. We are currently developing a plan to design, review, implement and refine internal control over financial reporting. We intend to assess the need to hire additional accounting and financial professionals with the requisite knowledge, experience and training to prepare, record and review accounting policies, processes and procedures, particularly revenue recognition, equity related transactions and other complex, judgmental areas, and prepare financial statements in accordance with generally accepted accounting principles and SEC reporting requirements. As the Acquisition occurred on December 17, 2014, our management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our internal control over financial reporting as of December 31, 2014.

Based on the foregoing and as permitted by Section 215.02 of the SEC's Compliance and Disclosure Interpretations, management is excluding its assessment of internal controls over financial reporting for the year ended December 31, 2014, which is the year the Acquisition was completed.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to the rules of the Securities and Exchange Commission.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance Matters," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Conduct and Ethics" in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Executive Officer and Director Compensation," in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management," and "Equity Compensation Plan Information" in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Transactions" and "Management and Corporate Governance Matters" in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Independent Public Accountants" in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

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	Description
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 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
3.1	Amended and Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
4.1	Form of Common Stock certificate (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.1@	2014 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.2@	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.3±	Collaboration Agreement by and between Pieris AG and Allergan Sales, LLC, dated as of August 21, 2009 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.4±*	Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of September 24, 2010.
10.5±	First Letter Agreement to Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of February 20, 2013 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.6±	Side Agreement to the Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur Inc., dated as of January 19, 2015 (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-202123) filed with the SEC on February 2, 2015).

Exhibit Number	Description
10.7±*	Collaboration Research and Technology Licensing Agreement by and between Pieris AG and Daiichi Sankyo Company Limited, dated as of May 31, 2011.
10.8±*	Development and License Agreement by and between Pieris AG and Cadila Healthcare Limited, dated as of October 7, 2013.
10.9±*	Joint Development and License Agreement by and between Pieris AG and Stelis BioPharma Private Limited, dated as of November 21, 2013.
10.10±*	Research and Licensing Agreement by and between Pieris AG and Technische Universität München, dated as of July 26, 2007.
10.11@	Form of Indemnification Agreement by and between the Registrant and each of its current directors and executive officers (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.12@	Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of August 30, 2009 (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.13@	Amendment to Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of March 12, 2012 (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.14@	Amended and Restated Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 17, 2014 (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.15@	Acknowledgement and Waiver Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 12, 2014 (incorporated by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.16@	Employment Agreement by and between the Registrant and Stephen S. Yoder, dated as of December 17, 2014 (incorporated by reference to Exhibit 10.15 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.17@	Management Agreement by and between Pieris AG and Claus Schalper, dated as of February 6, 2008 (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.18@	Consulting Agreement by and between Pieris AG and Claus Schalper, dated as of July 9, 2013 (incorporated by reference to Exhibit 10.18 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 17, 2014).
10.19@	Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of June 26, 2013 (incorporated by reference to Exhibit 10.18 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.20@	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of January 28, 2014 (incorporated by reference to Exhibit 10.19 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).

Exhibit Number	Description
10.21@	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of October 21, 2014 (incorporated by reference to Exhibit 10.20 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.22@	Management Agreement by and between Pieris AG and Dr. Laurent Audoly, dated as of May 18, 2010 (incorporated by reference to Exhibit 10.21 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.23@	Consulting Agreement by and between Pieris AG and Danforth Advisors, LLC, effective as of November 19, 2014 (incorporated by reference to Exhibit 10.22 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.24	Lease Agreement by and between Pieris AG and Födergesellschft IZB mbH, dated as of May 4, 2011 (incorporated by reference to Exhibit 10.23 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.25	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholder parties listed therein, dated as of November 12, 2012 (incorporated by reference to Exhibit 10.24 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.26	Amendment to Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed therein, dated as of March 4, 2014 (incorporated by reference to Exhibit 10.25 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.27	Participation Agreement (silent partnership agreement) between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated May 13, 2003 (incorporated by reference to Exhibit 10.26 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.28	Repayment Agreement by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of April 3, 2014 (incorporated by reference to Exhibit 10.27 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.29	Settlement Agreement (Accelerated Repayment Agreement) by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of December 11, 2014 (incorporated by reference to Exhibit 10.28 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.30	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed on Exhibit A thereto, dated as of April 14, 2014 (incorporated by reference to Exhibit 10.29 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.31	Consolidated Shareholders' Agreement 2014, Pieris AG, Freising, Germany, by and among Pieris AG and the Stockholders party thereto, dated October 10, 2014 (incorporated by reference to Exhibit 10.30 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.32	Investment Agreement, Pieris AG, Freising, Germany, by and among Pieris AG, Stephen Yoder and the Existing Shareholders party thereto, dated October 10, 2014 (incorporated by reference to Exhibit 10.31 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.33	Agreement, by and among Pieris AG and the Stockholders party thereto, dated December 5, 2014 (incorporated by reference to Exhibit 10.32 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).

Exhibit Number	Description
10.34	Split-Off Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014 (incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.35	General Release Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014 (incorporated by reference to Exhibit 10.34 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.36	Form of Securities Purchase Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the Purchasers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 23, 2014).
10.37	Form of Registration Rights Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 23, 2014).
10.38	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by Pieris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 23, 2014).
14.1*	Corporate Code of Ethics and Conduct and Whistleblower Policy.
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
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 Darlene Deptula-Hicks, Acting Chief Financial Officer, 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 Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith
** Furnished herewith
@ Management contract or compensatory plan or arrangement
± Confidential treatment requested

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

PIERIS PHARMACEUTICALS, INC.

Date: March 27, 2015

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 27, 2015
/s/ Darlene Deptula-Hicks Darlene Deptula-Hicks	Acting Chief Financial Officer, Secretary and Treasurer (*Principal Financial and Accounting Officer*)	March 27, 2015
/s/ Chau Khuong Chau Khuong	Chairman of the Board of Directors	March 27, 2015
/s/ Christina Takke, Ph.D. Christina Takke, Ph.D.	Director	March 27, 2015
/s/ Michael Richman Michael Richman	Director	March 27, 2015
/s/ Steven Prelack Steven Prelack	Director	March 27, 2015

PIERIS PHARMACEUTICALS, INC.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Pieris Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Pieris Pharmaceuticals, Inc. (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pieris Pharmaceuticals, Inc. at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Dr. Napolitano
Wirtschaftsprüfer
[German Public Auditor]

/s/ Richter
Wirtschaftsprüfer
[German Public Auditor]

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Munich, Germany
March 27, 2015

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2014	**2013**
ASSETS		
Current assets:		
Cash and cash equivalents	$18,474,211	$3,689,382
Restricted cash	—	72,497
Trade accounts receivable	—	481,810
Other current assets	1,207,072	449,733
Prepaid expenses	109,332	60,477
Income tax receivable	14,810	66,479
Total current assets	19,805,425	4,820,378
Property and equipment, net	2,052,221	2,437,677
Deferred tax asset	26,522	18,877
Total assets	$21,884,168	$7,276,932

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2014	**2013**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade accounts payable	$ 1,260,015	$ 278,008
Accrued expenses	743,866	559,629
Other current liabilities	242,755	160,484
Bank loan, including accrued interest, current portion	1,270,605	206,490
Deferred revenues, current portion	—	544,562
Deferred tax liabilities	26,522	18,877
Total current liabilities	3,543,763	1,768,051
Accrued expenses, non-current	333,988	379,942
Convertible stockholder loan, including accrued interest, net of current portion	—	3,098,502
Bank loan, including accrued interest, net of current portion	—	1,445,430
Total liabilities	3,877,751	6,691,925
Stockholders' equity		
Common stock, $0.001 par value per share, 300,000,000 shares authorized and 29,279,522 and 11,828,974 shares issued and outstanding at December 31, 2014 and 2013	29,280	11,829
Preferred stock, $0.001 par value per share, 10,000,000 shares authorized and no shares issued and outstanding at December 31, 2014 and 2013	—	—
Additional paid-in capital	84,627,283	57,608,337
Receivable from issuance of shares	—	(121,801)
Accumulated other comprehensive loss	(843,097)	(956,274)
Accumulated deficit	(65,807,048)	(55,957,084)
Total stockholders' equity	18,006,417	585,007
Total liabilities and stockholders' equity	$ 21,884,168	$ 7,276,932

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2014	**2013**
Revenues	$ 5,365,054	$ 12,427,292
Operating costs and expenses		
Research and development	(5,600,421)	(9,411,856)
General and administrative	(6,962,891)	(2,461,610)
	(12,563,312)	(11,873,466)
Income (loss) from operations	(7,198,257)	553,826
Other income (expense)		
Interest expense	(2,654,727)	(493,937)
Other income, net	3,002	6,307
	(2,651,725)	(487,630)
Income (loss) before income taxes	(9,849,982)	66,196
Income tax benefit	18	—
Net income (loss)	$ (9,849,964)	$ 66,196
Net income (loss) per share		
Basic and diluted	$ (0.71)	$ 0.01
Weighted average number of common shares outstanding		
Basic and diluted	13,872,390	11,828,974

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Years ended December 31,	
	2014	**2013**
Net income (loss)	$(9,849,964)	$66,196
Other comprehensive loss		
Foreign currency translation adjustments	113,176	23,109
Total other comprehensive income (loss), after tax	113,176	23,109
Comprehensive income (loss) attributable to the owners of Pieris Pharmaceuticals, Inc.	$(9,736,788)	$89,305

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common shares		Additional paid-in capital	Receivable from issuance of shares	Accumulated other comprehensive loss	Accumulated deficit	Total equity
	No. of shares	Share capital					
Balances as of January 1, 2013	11,828,974	$11,829	$57,608,337	$(121,801)	$(979,383)	$(56,023,280)	$ 495,702
Net income (loss)	—	—	—	—	—	66,196	66,196
Foreign currency translation adjustment	—	—	—	—	23,109	—	23,109
Balances as of December 31, 2013	11,828,974	11,829	57,608,337	(121,801)	(956,274)	(55,957,084)	585,007
Net income (loss)	—	—	—	—	—	(9,849,964)	(9,849,964)
Foreign currency translation adjustment	—	—	—	—	113,176	—	113,176
Beneficial conversion feature	—	—	2,236,581	—	—	—	2,236,581
Series C Shares Conversion	5,008,870	5,009	4,254,096	121,801	—	—	4,380,906
Issuance of Series C Cash Shares net $76,367 in offering costs	5,662,167	5,662	7,336,414	—	—	—	7,342,077
Issuance of Common Stock net $1,595,832 in offering costs	6,779,510	6,780	11,956,408	—	—	—	11,963,188
Stock-based compensation expense			571,382				571,382
Issuance of Warrants	—	—	664,064	—	—	—	664,064
Balances as of December 31, 2014	29,279,522	$29,280	$84,627,283	$ —	$(843,097)	$(65,807,048)	$18,006,417

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net income (loss)	$ (9,849,964)	$ 66,196
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation	366,979	384,677
Stock-based compensation	571,382	—
Warrants issued in Private Placement	664,064	—
Non-cash interest expense	2,589,025	414,269
Changes in operating assets and liabilities:		
Restricted cash	70,026	114,260
Trade accounts receivable	465,385	(337,483)
Prepaid expenses	(58,239)	1,049
Other assets	(911,289)	691,681
Trade accounts payable	1,115,987	(549,405)
Accrued and other liabilities	(136,997)	(3,846,904)
Income taxes	47,940	(14,822)
Net cash used in operations	(5,065,701)	(3,076,482)
Cash flows from investing activities:		
Purchase of property and equipment	(267,406)	(49,471)
Net cash used in investing activities	(267,406)	(49,471)
Cash flows from financing activities:		
Issuance of Common Stock, net of issuance costs	11,963,188	—
Issuance of Preferred Stock—series C, net of issuance costs	7,342,077	—
Proceeds from convertible stockholder loan	1,210,100	327,210
Repayment of debt	(181,515)	—
Net cash provided by financing activities	20,333,850	327,210
Effect of exchange rate change on cash and cash equivalents	(215,914)	161,047
Net increase in cash and cash equivalents	14,784,829	(2,637,696)
Cash and cash equivalents at beginning of year	3,689,382	6,327,078
Cash and cash equivalents at end of year	$18,474,211	$ 3,689,382
Supplemental cash flow disclosures:		
Cash paid for interest	$ 71,757	$ 79,668
Cash received (paid from) for income taxes	$ 51,651	$ 17,413
Noncash investing and Financing Activities:		
Conversion from debt to equity	$ 4,380,906	$ —

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

1. Corporate Information

Pieris Pharmaceuticals, Inc. was founded in May 2013 and is a holding company. On December 17, 2014 Pieris AG (a German company which was founded in 2001 by Prof. Dr. Arne Skerra, Professor at the Technical University of Munich, Germany, and Claus Schalper) became a wholly owned subsidiary of Pieris Pharmaceuticals, Inc., which was previously named Marika Inc. pursuant to a share exchange transaction (the "Acquisition"). For further information on the Acquisition refer to Note 3 *Acquisition*. The registered office of Pieris Pharmaceuticals, Inc. and the corporate headquarters and research facility of Pieris AG are located in Freising-Weihenstephan, Germany. Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris AG, was formed on February 14, 2014 to conduct research and development in Australia.

Pieris Pharmaceuticals, Inc. and its consolidated subsidiaries (the "Company") is a clinical-stage biopharmaceutical company dedicated to the discovery and development of their Anticalin® class of biotherapeutics for patients with diseases in which the Company believes there is high unmet medical need.

The Company's core Anticalin® technology and platform was developed in Germany, and the Company has partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India.

2. Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying financial statements were prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). All significant intercompany balances and transactions have been eliminated in the consolidation.

Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses in the financial statements and disclosures in the accompanying notes. Actual results and outcomes could differ materially from management's estimates, judgments and assumptions.

Foreign Currency Translation

The Company's reporting currency is U.S. dollars. During the years ended December 31, 2014 and 2013, the Company had operations in Germany with a functional currency of the euro, in Australia with a functional currency of the Australian dollar and in the U.S. with a functional currency of the U.S. dollar. All amounts in the financial statements where the functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows:

- assets and liabilities at period-end rates;
- income statement accounts at average exchange rates for the period; and
- components of equity at historical rates.

Gains and losses from translation of the financial statements into U.S. dollars are recorded in stockholders' equity as a component of other comprehensive loss. Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as general and administrative expenses in the Statements of Operations.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash on deposit in banks and other cash invested temporarily in money-market funds that are highly liquid and have an original maturity of less than 90 days at the date of purchase.

The Company held $0 and $72,497 in restricted cash as of December 31, 2014 and 2013, respectively. Such bank balances in 2013 related to prepayments received by the Company pursuant to EU grants under the EUROCALIN program (see Note 4 *Revenue*). These amounts were restricted to cover future obligations to members of the EUROCALIN consortium; they were not available for use by the Company.

Fair Value of Financial Instruments

ASC Topic 820 *Fair Value Measurement* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The Company's cash equivalents consist of highly liquid money market funds and are measured at fair value on a recurring basis. These funds are classified as Level 1 in the fair value hierarchy because they are valued using quoted prices for the periods ended December 31, 2014 and 2013. The carrying amounts of $4,800,573 and $3,307,520 as of December 31, 2014 and December 31, 2013, respectively, equal the fair value of the cash equivalents.

The Company's other financial instruments include debt instruments (bank loan) and are classified as Level 2 within the fair value hierarchy. The fair value of these instruments was determined using the discounted cash flow method based on contractual cash flows and the current rate at which debt with similar terms could be issued. The fair values for these debt instruments approximated carrying values as of December 31, 2014 and 2013.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that subject the Company to concentrations of credit risk include cash and cash equivalents and trade accounts receivable. The Company maintains cash and cash equivalents with various major financial institutions. The Company maintains deposits and owns money market funds only in highly rated financial institutions to minimize the credit risk from the financial institutions. Management periodically reviews the credit standing of these financial institutions and believes that the Company is not exposed to significant credit risk from the institutions in which those deposits are held and through which money-market funds are owned at December 31, 2014 and 2013.

As of December 31, 2014, the Company has no trade accounts receivable. See Note 4 *Revenue*, for additional information regarding the Company's collaboration agreements.

The Company relies on third parties to conduct preclinical and clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, the Company may not be able to obtain regulatory approval for the Company´s drug candidates and the Company's business could be substantially impacted. Furthermore, the Company is exposed to the risks associated with third parties formulating and manufacturing its preclinical and clinical drug supplies and any approved product candidates. The development and commercialization of any of its drug candidates could be stopped, delayed or made less profitable if those

third parties fail to provide the Company with sufficient quantities of such drug candidate or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements and prices.

In line with such third-party risk, the Company depends significantly on the Research and Licensing Agreement (or the "TUM License Agreement") with Technische Universität München "TUM" or "Technical University Munich"), under which certain intellectual property rights are exclusively licensed to the Company. In the event that the TUM License Agreement is terminated by TUM, the Company would be significantly hampered in its efforts to develop and commercialize, as well as to sub-license, the drug candidates covered by such exclusive license.

Trade Accounts Receivable

Trade accounts receivable are recorded net of allowances for doubtful accounts and represent amounts due from third parties and collaboration partners. Management monitors and evaluates collectability of receivables on an ongoing basis and considers whether an allowance for doubtful accounts is necessary. Management determined that no such reserve is needed as of December 31, 2014 and 2013. Historically, the Company has not had collectability issues with third parties and collaboration partners.

Property and Equipment

Property and equipment are recorded at acquisition cost, less accumulated depreciation and impairment. Depreciation on property and equipment is calculated using the straight-line method over the remaining estimated useful lives of the assets. The estimated useful life of the different groups of property and equipment is as follows:

Asset Classification	Estimated useful life (in years)
Leasehold improvements	5 - 13
Laboratory equipment	1 - 14
Office and computer equipment	1 - 15

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. In performing an impairment review, the Company estimates undiscounted cash flows from products that are covered by these assets. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value. No such impairments were recorded during the years ended December 31, 2014 or 2013.

Revenue Recognition

The Company has entered into several licensing and development agreements with collaboration partners for the development of Anticalin® therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include (i) licenses, or options to obtain licenses, to the Company's Anticalin technology and (ii) research activities to be performed on behalf of the collaborative partner. Payments to the Company under these agreements may include upfront fees (which include license and option fees), payments for research activities, payments based upon the achievement of certain milestones and royalties on product sales. There are no performance, cancellation, termination or refund

provisions in any of the arrangements that could result in material financial consequences to the Company. The Company follows the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

Multiple-Element Arrangements

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

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. The Company has used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because the Company does not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, the Company considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the Company's best estimate of selling price, the Company evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

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

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

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

In arrangements where options to obtain additional licenses are considered substantive, the Company determines whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and incremental discount, the option is considered a deliverable in the arrangement. However, if not

priced at a discount, the elements included in the arrangement are considered to be only the non-contingent elements. When a collaborator exercises an option to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and the Company applies the multiple-element revenue recognition criteria to determine accounting treatment. All of the Company's agreements with options have been determined to include substantive options.

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

Milestone Payments and Royalties

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

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

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

Government Grants

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

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

Research and Development

Research and development costs are charged to expense as incurred. Research and development expenses consist of expenses incurred in performing research and development activities which are directly attributable to the creation of the Company´s Anticalin® class of biotherapeutics, including salaries and benefits; overhead expenses, including facilities expenses; materials and supplies; preclinical expenses; clinical trial and related clinical manufacturing expenses; depreciation of equipment; contract services; and other outside expenses. Legal fees incurred for patent application costs have been charged to expense and reported in research and development expenses.

Income Taxes

The Company applies ASC 740—*Income Taxes*, which established financial accounting and reporting requirements for the effects of income taxes that result from the Company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Where the Company determines that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance.

Share-based Payments

The Company measures share-based payments in accordance with ASC Topic 718, Compensation—Stock Compensation. 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 estimated forfeitures.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes model, require the input of subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, expected life of the award and forfeitures.

The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero.

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities, and other factors due to the lack of historic information of the Company´s common stock. The expected life of stock-based options is the period of time for which the stock-based options are expected to be outstanding. Given the lack of historic exercise data, the expected life is determined using the "simplified method" which is

defined as the midpoint between the vesting date and the end of the contractual term. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company assesses the forfeiture rate on an annual basis and revises the rate when deemed necessary. Refer to Note 9 *Stock-Based Compensation,* for further information.

Warrants to Purchase Common Stock

Outstanding warrants are standalone instruments that are not puttable or mandatorily redeemable by the holder and are classified as equity awards. The Company measures the fair value of the awards using the Black-Scholes option pricing model as of the measurement date using assumptions that are based on the individual characteristics of the warrants on the valuation date, as well as assumptions for future events, expected volatility, expected life, yield, and risk-free interest rate. Issued warrants are recorded at fair value as a reduction in additional paid-in capital of the common stock issued. Refer to Note 10 *Warrants* for further information.

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 asses performance. The Company operates as a single segment dedicated to the discovery and development of biotechnological applications and accordingly, views its operations and manages its business in one operating segment.

Basic and Diluted Earnings per Share

Basic and diluted income (loss) per common share have been computed by dividing the income (losses) applicable to common stock by the weighted average number of common shares outstanding. The Company's basic and fully diluted earnings per share ("EPS") calculations are the same because the increased number of shares that would be included in the diluted calculation from assumed exercise of stock equivalents would be anti-dilutive to the net loss in 2014 and there were no stock equivalents granted in 2013.

Adoption of New Accounting Standards

In February 2013, the FASB issued Accounting Standards Update ("ASU") No. 2013-02, *"Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income"* ("ASU 2013-02"). Under ASU 2013-02, an entity is required to provide information about the amounts reclassified out of Accumulated Other Comprehensive Income ("AOCI") by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 does not change the current requirements for reporting net income or other comprehensive income in the financial statements. ASU 2013-02 became effective for non emerging growth companies for reporting periods

beginning after December 15, 2012. For the Company, ASU 2013-02 became effective on January 1, 2014 and its adoption did not have an effect on the Company's consolidated financial statements.

In February 2013, the FASB issued ASU No. 2013-04, "*Liabilities (Topic 405)—Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date"* ("ASU 2013-04"). The amendments in this update provide guidance for the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation within the scope of this update is fixed at the reporting date, except for obligations addressed within existing guidance in U.S. GAAP. The guidance requires an entity to measure those obligations as the sum of the amount the reporting entity agreed to pay on the basis of its arrangement among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The guidance in this update also requires an entity to disclose the nature and amount of the obligation as well as other information about such obligations. The requirements of ASU 2013-04 became effective for non emerging growth companies for reporting periods beginning after December 15, 2013. For the Company, ASU 2013-04 became effective on January 1, 2014 and its adoption did not have an effect on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In March 2013, the FASB issued ASU No. 2013-05, *"Foreign Currency Matters (Topic 830): Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity"* ("ASU 2013-05"). The amendments in ASU 2013-05 provide guidance on releasing Cumulative Translation Adjustments ("CTA") when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business within a foreign entity. In addition, these amendments provide guidance on the release of CTA in partial sales of equity method investments and in step acquisitions. For public entities, the amendments are effective on a prospective basis for fiscal years and interim reporting periods within those years, beginning after December 15, 2013 and for periods beginning after December 15, 2014 for non-public companies and emerging growth companies. The amendments should be applied prospectively to de-recognition events occurring after the effective date. Prior periods should not be adjusted and early adoption is permitted. For the Company, ASU 2013-05 will become effective on January 1, 2015 and the Company does not expect these provisions to have a material impact on the Company's consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, *"Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists"* ("ASU 2013-11") (a consensus of the FASB Emerging Issues Task Force), which requires an entity to present an unrecognized tax benefit as a reduction of a deferred tax asset for a net operating loss ("NOL") carryforward, or similar tax loss or tax credit carryforward, rather than as a liability when:

- the uncertain tax position would reduce the NOL or other carryforward under the tax law of the applicable jurisdiction; and
- the entity intends to use the deferred tax asset for that purpose.

The ASU does not require new disclosures and is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013 for public companies and for periods beginning after December 15, 2014 for non-public companies and emerging growth companies. Early adoption and retrospective application are permitted. For the Company, ASU 2013-11 will become effective on January 1, 2015, and the Company is in the processes of evaluating of the impact the adoption will have on its consolidated financial statements.

In May 2014 the FASB issued ASU No. 2014-09 "*Revenue from Contracts with Customers"* ("ASU 2014-09"). ASU 2014-09 affects contracts with customers to transfer goods or services or contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. ASU 2014-09 will supersede

the revenue recognition requirements in Topic 605, *Revenue Recognition*, and most industry-specific guidance. ASU 2014-09 also supersedes some cost guidance included in Subtopic 605-35, *Revenue Recognition—Construction-Type and Production-Type Contracts*. In addition, the existing requirements for the recognition of a gain or loss on the transfer of nonfinancial assets that are not in a contract with a customer (*e.g.*, assets within the scope of Topic 360, *Property, Plant, and Equipment*, and intangible assets within the scope of Topic 350, *Intangibles—Goodwill and Other*) are amended to be consistent with the guidance on recognition and measurement in ASU 2014-09.

The core principle of the guidance is that an entity should recognize revenue consistent with the performance obligation to transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

For the Company, ASU 2014-09 will become effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early application is not permitted. The Company is in the process of evaluating the impact the adoption will have on the consolidated financial statements.

In June 2014 the FASB issued ASU No. 2014-12 "*Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period"* ("ASU 2014-12").

The amendments in ASU 2014-12 apply to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. That is the case when an employee is eligible to retire or otherwise terminate employment before the end of the period in which a performance target (for example, an initial public offering or a profitability target) could be achieved and still be eligible to vest in the award if and when the performance target is achieved.

For all entities, the amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The effective date is the same for both public entities and all other entities.

Entities may apply the amendments in this Update either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this Update as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. The Company is still evaluating the impact of the adoption of ASU 2014-12 on the consolidated financial statements.

In January 2015 the FASB issued ASU No. 2015-01 *"Income Statement—Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items"* ("ASU 2015-01").

The amendments in ASU 2015-01 eliminates from U.S. GAAP the concept of extraordinary items. Subtopic 225-20, Income Statement—Extraordinary and Unusual Items, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. This guidance is effective for the Company for annual periods ending after December 15, 2015. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The Company is currently assessing the expected impact, if any, that ASU 2015-01 will have on the consolidated financial statements.

In February 2015, the FASB issued ASU No. 2015-02, *"Consolidation (Topic 810): Amendments to the Consolidation Analysis"* ("ASU 2015-02"). The amendments in ASU 2015-02 are intended to improve targeted areas of consolidation guidance for legal entities such as limited partnerships, limited liability corporations, and securitization structures (collateralized debt obligations, collateralized loan obligations, and mortgage-backed security transactions). This guidance is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December, 15, 2017. The Company is currently evaluating the impact of ASU 2015-02 will have on the consolidated financial statements.

The Company has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

3. Acquisition

On December 17, 2014, Pieris AG, the Company (formerly known as Marika Inc.) and the former shareholders of Pieris AG entered into an Acquisition Agreement (the "Acquisition Agreement"). Pursuant to the Acquisition Agreement, the former shareholders of Pieris AG contributed all of their equity interests in Pieris AG in exchange for 20,000,000 shares of the Company´s common stock, which resulted in Pieris AG becoming a wholly owned subsidiary of the Company (the "Acquisition"). Upon the closing of the Acquisition and prior to the closing of the December 2014 private placement financing, the former stockholders of Pieris AG collectively owned approximately 89% of outstanding shares of the Company´s common stock.

On December 5, 2014, Pieris Pharmaceuticals, Inc. completed a 2.272727-for-1 forward split of its common stock in the form of a share dividend, with the result that 6,100,000 shares of common stock outstanding immediately prior to the stock split became 13,863,647 shares of common stock outstanding immediately thereafter. Effective as of December 16, 2014, Pieris Pharmaceuticals, Inc. amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to "Pieris Pharmaceuticals, Inc." and increase its authorized capital stock from 75,000,000 shares of common stock, par value $0.001 per share, to 300,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value $0.001 per share. On December 17, 2014, Pieris Pharmaceuticals, Inc. transferred its pre-Acquisition assets and liabilities to its former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris Pharmaceuticals, Inc. common stock.

In accordance with FASB, ASC Section 805 entitled "Business Combinations," Marika Inc. does not meet the definition of a business as it is a non-operating shell company. As a result, the Acquisition has been accounted for as a reverse-merger and recapitalization. Pieris AG is the acquirer for financial reporting purposes and Pieris Pharmaceuticals, Inc. is the acquired company. Consequently, the assets and liabilities and the operations reflected in the historical financial statements prior to the Acquisition are those of Pieris AG and are recorded at the historical cost basis of Pieris AG, and the consolidated financial statements after completion of the Acquisition include the assets and liabilities and results of operations of the combined Company. Share capital prior to the closing of the Acquisition has been retroactively adjusted to reflect the legal capital of Pieris Pharmaceuticals, Inc.

4. Revenue

General

The Company has not generated revenue from product sales. The Company has generated revenue pursuant to (i) license and collaboration agreements, which include upfront payments for licenses or options to obtain

licenses, payments for research and development services and milestone payments, and (ii) government grants, which are shown in the table below for periods specified:

	Years ended December 31,	
	2014	2013
License fees	$ 473,039	$ 5,159,425
Research and development services	876,619	3,591,855
Milestone payments	3,184,988	1,128,630
Government grants	830,408	2,547,382
Total Revenue	$5,365,054	$12,427,292

Revenue from two collaboration partners and from one government grant exceeded 10% of total revenue, amounting to $2,981,992, $1,354,861 and $714,388, respectively, in the year ended December 31, 2014 and $5,573,441 $4,168,278 and $2,430,358, respectively, in the year ended December 31, 2013.

Collaborations and Other Agreements

Allergan Inc.

In August 2009, pursuant to an agreement with Allergan Inc. ("Allergan"), the Company granted Allergan a worldwide exclusive license to develop and commercialize certain drug candidates for the treatment and prevention of ocular diseases. Allergan is responsible for the research, development, manufacturing and commercialization of any products resulting from the license. The Company received a non-refundable upfront payment of $10 million upon execution of the contract in 2009 and is entitled to receive up to an aggregate of $13 million in milestone payments upon the achievement of certain commercial milestones or patents granted to the Company by the United States Patent and Trademark Office that cover a product licensed to Allergan.

At the inception of the agreement, the Company recognized revenue from the upfront license payment because, based on the stage of development of the licensed product delivered and the development capabilities of Allergan, the Company determined that the license had standalone value. Through December 31, 2014, none of the milestones had been achieved and, as such, the Company has not recognized milestone-related revenues from the collaboration agreement with Allergan.

Daiichi Sankyo Co., Ltd.

In May 2011, the Company entered into an agreement with Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"), under which the Company will use its proprietary Anticalin® scaffold technology to identify drug candidates against certain targets selected by Daiichi Sankyo, with further development and commercialization performed by Daiichi Sankyo. For any targets selected by Daiichi Sankyo, the Company granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company. In March 2013 and June 2014, the Company transferred further development responsibility for the two collaboration projects to Daiichi Sankyo.

Upon execution of the agreement, Daiichi Sankyo paid the Company a non-refundable upfront payment in the amount of $10.1 million in consideration for the licenses, and for each licensed product the Company is entitled to receive potential milestone payments of $98.7 million, plus royalties on the commercial sales of any commercial products. The total milestones are categorized as follows: research milestones of $2.8 million; development milestones of $40.5 million; commercial milestones of $54.5 million; additional diagnostic milestones of $0.9 million. At the inception of the agreement, these milestones were determined to be substantive as there was substantial uncertainty the milestones would be achieved, they would require substantial performance from the entity, and the consideration was reasonable relative to other deliverables. The agreement

includes provisions for the Company to provide research services funded by Daiichi Sankyo at agreed upon full-time employee rates during the initial identification and research period.

In accordance with the guidance in ASC 605-25, the Company identified the licenses and research funding as deliverables at the inception of the arrangement. The Company has determined that the licenses and research services provided by the Company represent one unit of accounting because, based on the stage of development of the licensed product the research services provided by the Company to identify drug candidates using the Company's proprietary Anticalin® technology against Daiichi Sankyo's selected targets were necessary before the licenses would have any standalone value. Therefore, the total arrangement consideration was recognized over the estimated period of substantial involvement, which was determined to be the period during which the Company was required to provide research services to discover drug candidates against targets identified. The Company estimated that this period would be approximately two years. For the year ended December 31, 2014, the Company recognized $3.0 million in revenues related to the Daiichi Sankyo collaboration, of which $2.3 million related to the achievement of milestones. For the year ended December 31, 2013, the Company recognized $5.6 million in revenues, of which $1.1 million related to the achievement of milestones.

The milestone payments in 2014 are based on successful *in vitro* and *in vivo studies* and for the initiation on a toxicity study in non-human primates. The milestone payments in 2013 resulted from the achievement of a success milestone, the hand-over of a collaboration project to Daiichi Sankyo. The milestones could not be achieved solely upon the passage of time. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. Therefore, each of the milestone payments were recognized in their entirety as revenues during the respective years ended December 31, 2014 and 2013 in which they were received.

Sanofi-Aventis and Sanofi-Pasteur

In September 2010, the Company entered into an agreement with Sanofi-Aventis and Sanofi Pasteur (together, "Sanofi"), under which the Company agreed to apply its proprietary Anticalin® technology to identify drug candidates against certain targets selected by Sanofi, with further development and commercialization performed by Sanofi. The agreement included the initial identification of two targets by Sanofi, with options to select up to four additional targets. For any targets selected by Sanofi, the Company granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company In addition to the two initial targets selected by Sanofi, Sanofi exercised one of the four options and received a license. The remaining three options expired unexercised.

Upon execution of the agreement, Sanofi paid the Company an upfront payment of $4.9 million in consideration for licenses on the first two targets and options to select an additional four licenses on other targets (with each option requiring an additional upfront payment upon exercise). Additionally, for each licensed product, the Company is entitled to receive milestone payments up to $55.9 million, plus royalties on the sales of any commercial products. The total milestones are categorized as follows: research milestones of $2.1 million; development milestones of $32.1 million; and commercial milestones of $21.8 million. At the inception of the agreement, these milestones were determined to be substantive because (i) there was substantial uncertainty the milestones would be achieved, (ii) they would require substantial performance from the entity, and (iii) the consideration was reasonable relative to other deliverables. The agreement includes provisions for the Company to provide research services funded by Sanofi at agreed upon full-time employee equivalent rates during the initial identification and research period.

In accordance with the guidance in ASC 605-25, the Company identified the licenses, options to obtain additional licenses and research funding as deliverables at the inception of the arrangement. The options were

considered to be substantive at the inception of the agreement. Factors considered in determining the options were substantive were whether (i) Sanofi could obtain the overall objective of the agreement without exercising any options, (ii) Sanofi was able to obtain value from the initial licenses obtained without exercising any options, (iii) the cost to exercise the options was significant to the total upfront payment of $4.9 million for two licenses and four options, and (iv) exercising the option created additional financial commitments for Sanofi or imposed economic penalties on Sanofi.

The Company has determined that, for each program selected by Sanofi, the license and research services provided by the Company represent one unit of accounting because, based on the stage of development of the licensed product, the research services provided by the Company to identify drug candidates using the Company's proprietary Anticalin® technology against Sanofi's selected targets were necessary before the licenses would have any standalone value.

The estimated selling prices for the licenses in the agreement are the Company's best estimate of selling price and were determined based on market conditions and entity-specific factors such as considerations of preclinical and clinical testing results and the Company's pricing practices and pricing objectives. The estimated selling price of research services are the Company's best estimate of selling price and are determined based on market conditions and entity-specific factors such as internal cost considerations and the Company's pricing practices and pricing objectives.

At inception, the total arrangement consideration of $8.1 million (which comprises the $4.9 million upfront payment and the expected fees for the research services to be provided under the remainder of the arrangement) was allocated to the deliverables based on the relative selling price method as follows: $3.5 million to the licenses, $1.4 million to the four options to acquire additional licenses and $3.2 million to the estimated research services to be provided. As the license and research services were determined to be one unit of accounting, the consideration allocated to each license is recognized over the period of substantial involvement, which was determined to be the period during which the Company was required to provide research services to discover drug candidates against targets identified, approximately two years. The Company reassessed the estimated term at the end of each reporting period. At the end of 2012, the Company determined that the required research term for one of the initial terms would extend to a period of 40 months, and management updated the estimated required service period to amortize the remaining deferred upfront payment over the new term. Two of the four options expired un-exercised in 2011, and as a result the Company recognized $0.7 million of revenue upon expiration. The option term for the remaining two options was extended to February 2013, and Sanofi exercised one option to obtain an additional license. For the exercised option, the allocated consideration of $0.35 million for the option and the $1.4 million payment of the exercise price were deferred and amortized over the expected required service period of approximately two years. The program covered by the exercised option was terminated in December 2013, and accordingly, the Company recognized the remaining deferred revenue upon termination. The remaining option expired in February 2013 and the allocated consideration of $0.35 million was recognized into revenue at the time of expiration.

For the years ended December 31, 2014 and 2013, the Company recognized $1.4 million and $4.2 million, respectively, related to the Sanofi collaboration. In 2014, $0.9 million was recognized related to the achievement of milestones. The milestone payments in 2014 result from a positive review of a broad range of in *vitro, in vivo* and chemistry, manufacturing and control ("CMC") data. No milestones had been achieved through December 31, 2013.

Stelis BioPharma

The Company entered into an agreement with Stelis BioPharma Private Limited ("Stelis") on November 21, 2013, pursuant to which, the Company collaborates with Stelis in the development of certain Anticalin® drug candidates, primarily for use in the treatment, palliation or prevention of ophthalmology-related diseases. Both parties may establish a joint venture for further development and commercialization of one or more such

products in the future. The Company granted Stelis a royalty-free, co-exclusive license within a specified field. Stelis is responsible for further developing the chosen candidates and taking them through certain development stages and bears all related expenses.

The license granted refers to products (Anticalin® proteins) which have already been researched and developed by the Company independently before the arrangement with Stelis.

No payments have been received under this agreement, and thus, no revenues have been recognized.

Cadila Healthcare Limited

On October 7, 2013, the Company entered into an agreement with Cadila Healthcare Limited ("Zydus"), under which the Company granted to Zydus an exclusive, royalty-bearing license to use, sell, and import/export certain Anticalin® drug products, including the right to grant sublicenses in a specified territory. Zydus also received a co-exclusive royalty-free license to research, develop and produce a product in the specified territory as well as to conduct research and manufacture a product in specified field, as long as such activities are solely the development or commercialization in Zydus' territory as defined in the agreement. The Company received under the agreement a non-exclusive, royalty-free, world-wide license to exploit know-how and intellectual property that was made available to Zydus before October 7, 2013. Both parties agreed upon several milestone payments as well as a sharing of out-licensing revenue.

No payments have been received under this agreement, and thus, no revenues have been recognized.

Other Arrangement

The Company entered into a materials transfer agreement, which is effective as of January 14, 2013. Under this arrangement the partner tests certain Company Anticalin® proteins with certain proprietary materiel, conducts certain purification and characterization studies on the resulting combined products and subsequent preclinical studies. The Company produces and supplies Anticalin proteins and receives research reports from the partner. Each party is otherwise responsible for its own costs and expenses. The Company recognized research and development services revenue of $138,091 in the year ended December 31, 2013 under this arrangement. No revenues were recognized under this agreement for the year ended December 31, 2014.

Government Grants

BioCluster m4

In 2011 the Company applied for a government grant from the German Federal Ministry for Education and Research for the project "Spitzencluster m4, Cooperation personalized medicine: 'Preclinical development of PRS-110 an Anticalin® targeted against c-Met as a monovalent antagonist in the field of oncology (PM18).'" The funding rate amounts 40% of the actual costs incurred, with an aggregate cap of $1,375,017 for the approval period from February 1, 2012 to September 30, 2014. The amounts received are non-refundable, and the grant funds may only be claimed for costs incurred within the approval period.

The payments are received quarterly in arrears based on expenses already incurred. The Company received $116,020 and $117,023 for the years ended December 31, 2014 and 2013, respectively, which was recorded as grant revenue.

Seventh Research Framework Program ("FP7")—Collaborative Project "EUROCALIN—European consortium for antiCALINs as next generation high-affinity protein therapeutics" ("EUROCALIN")

EUROCALIN is a program that started in August 2011 with the objective of developing and producing new high-affinity protein scaffolds for therapeutic use. The focus is on the development of non-immunoglobulin

protein scaffolds as alternatives to antibodies and oligo-nucleotides. The grant involves a consortium of ten companies and universities in Europe and was initiated for a collaboration focused on attaining and completing initial clinical development of a novel Anticalin® therapeutic. The consortium is seeking to develop, manufacture and clinically test an Anticalin specific for hepcidin. The program is a small molecule enhancers ("SME") targeted project, which is funded by the European Union ("EU") in the amount of $7,260,600 and also includes a respective funding rate of approximately 64% of the eligible costs occurred in connection with the research project. All payments received from the EU in connection with the grant are non-refundable. Under this grant agreement, the Company is the coordinator. The EU has scheduled three tranches of payments. The first tranche (pre-financing) was received as of December 7, 2011 and the second tranche as of August 4, 2013. The third tranche will be received upon completion of the program. The Company, as the coordinator, receives all payments from the grant. The other members of the consortium are entitled to payments based on submission of invoices of eligible costs. The Company pays the other members of the consortium based on the eligible costs.

The Company has received the following amounts:

	Years ended December 31,	
	2014	2013
Amounts received	$ —	$2,915,559
Revenue from grant	$714,388	$2,430,358

The following balance sheet items relate to the FP7 agreement:

	December 31,	
	2014	2013
Other current assets (receivables from FP7 grant)	$857,489	$261,568
Cash (restricted cash)	$ —	$ 72,497
Deferred revenue	$ —	$ 69,444

5. Property and Equipment, net

Property and equipment are summarized as follows:

	December 31,	
	2014	2013
Leasehold improvements	$ 50,791	$ 57,779
Laboratory equipment	3,840,368	4,093,704
Office and computer equipment	343,835	389,368
Property and equipment at cost	4,234,994	4,540,852
Accumulated depreciation	(2,182,773)	(2,103,175)
Property and equipment, net	$ 2,052,221	$ 2,437,677

Accumulated depreciation for each asset group is summarized as follows:

	Years ended December 31,	
	2014	2013
Leasehold improvements	$ 41,606	$ 37,904
Laboratory equipment	1,886,807	1,845,098
Office and computer equipment	254,360	220,172
Total accumulated depreciation	$2,182,773	$2,103,175

Depreciation expense was $366,979 and $384,677 for the years ended December 31, 2014 and 2013, respectively. There were no other changes in accumulated depreciation other than foreign currency impact.

6. Income Taxes

The income tax benefits are as follows:

	Years ended December 31,	
	2014	2013
Current	$18	$—
Total income tax benefit	$18	$—

The applicable U.S. statutory federal income tax rate was 34.00% for the year ended December 31, 2014. The applicable German statutory federal income tax rate was 29.13% for the year ended December 31, 2013 and December 31, 2014. The principal differences between income taxes computed at the U.S. statutory tax rate for the year ended December 31, 2014 and at the German statutory tax rate for the year ended December 31, 2013 and the respective effective tax rate are as follows:

	Years ended December 31,	
	2014	2013
Income tax expense (benefit) at the statutory federal income tax rate	$(3,348,994)	$ 19,280
Decrease in allowances on deferred tax assets	$(4,811,972)	$(37,210)
Differences local / Group tax rate	420,337	—
Nondeductible expenses	438,797	17,930
Correction of net operating loss carryforwards	7,307,952	—
Other	(6,102)	—
Total income tax expense (benefit)	$ 18	$ —

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:

	December 31,	
	2014	2013
Deferred tax assets		
Net operating loss carryforwards	$9,951,666	$16,859,179
Deferred revenue	—	138,378
Equity issuance cost	—	102,935
Bank loan	12,653	23,014
Intercompany Loan Australia	1,129	—
Total deferred tax assets	9,965,448	17,123,506
Valuation allowance	9,916,553	17,053,767
Net deferred tax assets	48,895	69,739
Deferred tax liabilities		
Useful life adjustment fixed assets	30,646	54,303
Adjustment accruals	8,811	15,436
Prepaid expenses	9,438	—
Total deferred tax liabilities	48,895	69,739
Net deferred tax asset/(liability)	$ —	$ —

The decrease in the valuation allowance of deferred tax assets is influenced by a foreign currency effect.

As of December 31, 2014 and 2013, the Company had net operating loss carryforwards on German corporate income tax of $34,168,814 and $57,795,357, respectively, and on trade tax of $34,168,814 and $56,420,412, respectively. The operating loss carryforwards generated are subject to restrictions under German tax law. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership. As a result of the Acquisition, the Company has lost $22,915,150 of the unused German corporate income tax loss carryforwards and $21,582,596 of the unused German corporate trade tax loss carryforwards existing or realized at the time of the Acquisition.

Management of the Company has evaluated the evidence bearing upon the realizability of its deferred tax assets, including the Company's history of operating losses, and has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, the deferred tax assets have been fully reserved to the extent not offset by deferred tax liabilities at December 31, 2014 and 2013. The valuation allowance decreased by $7,137,214 during the year ended December 31, 2014 primarily as a result of the forfeiture of the net operating loss carryforwards. As there are currently no significant uncertain tax positions, no liability for unrecognized tax positions have been recognized. The Company files tax returns in the U.S., Germany and Australia. In Germany the Company is generally no longer subject to tax examinations for years prior to 2013.

Tax field audit

On July 11, 2014, a tax field audit for the years 2010 to 2012 in accordance with §193 paragraph 1 AO under German law was announced by the tax office Freising. The tax field audit took place in July 2014. The results of the audit lead to a reduction of the Company's net operating loss carryforwards on German corporate income tax by a total of $619,820 and a reduction of the Company´s net operating loss carryforwards on German corporate trade tax by a total of $644,795 for the years under the tax audit.

7. Debt

Convertible Stockholder Loans

On November 12, 2012, the Company and several of its stockholders entered into an unsecured Convertible Stockholder Loan Agreement, which was subsequently amended in March 2014 (the "2012 Bridge Loan"). There were no outstanding principal or accrued interest balances under the 2012 Bridge Loan as of December 31, 2014 due to the conversion to equity as discussed below. The outstanding principal and accrued interest balance under the 2012 Bridge Loan as of December 31, 2013 was $2,753,200 and $345,302, respectively. The 2012 Bridge Loan specified a maturity date of December 31, 2015 and an interest rate of 12% per year through December 31, 2013 and a rate of 18% per year subsequent to December 31, 2013.

On April 14, 2014, the Company entered into a second bridge loan agreement (the "2014 Bridge Loan" and together with the 2012 Bridge Loan, the "Bridge Loans") with certain of its stockholders pursuant to which the Company received a commitment for financing in the aggregate amount of €2,000,000 ($2,420,200). The 2014 Bridge Loan included two tranches of available financing: (i) Tranche A of €1,500,000 ($1,815,150) and (ii) Tranche B of €500,000 ($605,050). In June 2014, the Company borrowed 67% of Tranche A, or €1,000,000 ($1,210,100). There were no outstanding principal or accrued interest balances under the 2014 Bridge Loan as of December 31, 2014 due to the conversion to equity as discussed below. Loan amounts outstanding under the 2014 Bridge Loan accrued interest at a rate of 12% per year and had a maturity date of December 31, 2015, after which the loan amounts would accrue interest at a rate of 18% per year.

The Bridge Loans did not contain financial or non-financial covenants. During the fourth quarter of 2014, the investors in the Bridge Loans exercised their option to convert all of the outstanding principal and interest

amounts under the Bridge Loan into shares. For more information refer to Note 8 *Stockholders´ Equity*. In 2014, $2,236,581 was recognized for a beneficial conversion feature related to the Bridge Loans within interest expense and additional paid in capital.

In accordance with the Bridge Loans, the Company recognized interest expense of $326,429 and $317,014 for the years ended as of December 31, 2014 and 2013, respectively. No principal or interest payments were made for the Bridge Loans in 2014 or 2013.

Four significant stockholders of the Company—Orbimed Private Investments III, LP, Gilde Europe Food & Agribusiness Fund B.V., The Global Life Science Ventures Funds (consists of The Global Life Science Venture Funds II GmbH & Co. KG, i.L. and The Global Life Science Venture Funds II Limited Partnership) and Coöperative AAC LS U.A. (Forbion B.V.)—are among the investors in Bridge Loans.

The Company recorded related-party interest expense concerning the Bridge Loan in the amounts set forth in the table below:

	Years ended December 31,	
	2014	2013
Orbimed Private Investments III, LP	$ 63,955	$ 78,411
The Global Life Science Ventures Funds	57,709	70,131
Gilde Europe Food & Agribusiness Fund B.V.	54,158	67,083
Coöperative AAC LS U.A. (Forbion B.V.)	28,288	34,930
Sum of related-party interest expense relating to the Convertible Bridge Loan	$204,110	$250,556

Unsecured Bank Loan

In May 2003, the Company signed an unsecured loan agreement (the "Bank Loan") under a silent partnership agreement with Technologie-Beteiligungs-Gesellschaft ("TBG"), a minority interest stockholder. On April 3, 2014 the Company and TBG signed a repayment agreement concerning the Company's repayment of its liabilities to TBG outstanding at December 31, 2013 in a total amount of €1.2 million ($1.65 million). The principal amount bears interest at a rate of 10.53%. Under the repayment agreement, the Company agreed to a payment schedule pursuant to which it would make semi-annual payments until 2016; however, on December 11, 2014, the Company and TBG entered into an accelerated repayment agreement. Pursuant to terms of the accelerated repayment agreement, conditioned upon closing of the Acquisition, the Company was obligated to pay €1,050,000 ($1.27 million), the outstanding amount under the repayment agreement, in two tranches as follows: €600,000 ($726,060) plus accrued interest on January 31, 2015 and €450,000 ($544,545) on March 31, 2015. Upon full payment of the accelerated repayment amount of €1,050,000 ($1.27 million), all claims of the Company and TBG against each other from or in connection with the silent partnership agreement dated May 13, 2003 and the repayment agreement entered into on April 3, 2014, were considered settled and repaid in full.

As of December 31, 2014 and 2013 outstanding principal under the Bank Loan was $726,060 and $1,032,450, respectively. Principal payments in an amount of $181,515 were made in 2014. No principal payments were made for in 2013. The key terms of the Bank Loan are as follows:

- The original maturity date of the Bank Loan was December 31, 2013.
- Interest at 8% per year was required to be paid on a semi-annual basis, which resulted in interest expense of $79,668, in 2013. In accordance with the repayment agreement dated April 3, 2014, interest at 10.53% was required to be paid on a semi-annual basis, which resulted in interest expense of $71,757 in 2014. The amounts reflected on the balance sheets in other current liabilities totaled $19,117 and $20,649 as of December 31, 2014 and 2013, respectively.

- A repayment fee of 30% and an additional interest premium of 6% (effective beginning June 2008) of the loan amount was due when the principal was paid, which resulted in total interest expense of $97,255 in 2013. Under the repayment agreement dated April 3, 2014, no additional interest expenses were recognized for 2014. The amounts reflected on the balance sheets in Bank Loan include accrued interest of $544,545 and $619,470 as of December 31, 2014 and 2013, respectively.
- 12% per year of the German GAAP net income, adjusted for certain items per the Bank Loan, is payable to TBG. As the adjusted German GAAP net income amounts for the Company were negative for all years, no amounts were recorded for this provision.
- There are no financial or non-financial covenants.

The following table summarizes the Company´s financial obligations for the next five years and thereafter as of December 31, 2014:

	2015	2016	2017	2018	2019	Thereafter	Total
Bank loan, including accrued interest	$1,270,605	$—	$—	$—	$—	$—	$1,270,605

8. Stockholders´ Equity

Common Stock

The Company has authorized 300,000,000 shares of common stock, par value $0.001 per share. As of December 31, 2014 there were 29,279,522 shares of common stock issued and outstanding. As a result of the Acquisition, the equity structure of the Pieris AG was retroactively adjusted using the exchange ratio established pursuant to the Acquisition Agreement to reflect the number of shares of the Company issued in the Acquisition. The retroactively adjusted shares as of December 31, 2013 were equivalent to 11,828,974 shares of common stock of the Company.

Each share of the Company´s common stock is entitled to one vote and all shares rank equally as to voting and other matters.

Dividends may be declared and paid on the common stock from funds legally available therefor, if, as and when determined by the Board of Directors.

Preferred Stock

The Company has authorized 10,000,000 shares of “blank check” preferred stock, par value $0.001 per share. There were no shares of preferred stock issued and outstanding during each of the years ended December 2014 and 2013. Shares of preferred stock may be issued in one or more series at such time or times and for such consideration as the Board of Directors may determine.

2014 Series C Financing

During the fourth quarter of 2014 and prior to the Acquisition, the Company completed a financing round and issued the equivalent of 10,671,037 shares of common stock. This financing included an issuance of the equivalent of 5,662,167 shares of common stock for aggregate cash proceeds of $7,442,897. Additionally, outstanding principal and interest related to the Bridge Loans ($4,380,906) was converted for the equivalent of 5,008,870 shares of common stock.

Acquisition

Immediately following the closing of the Acquisition, the Company´s outstanding shares of common stock (on a fully diluted basis) were as follows:

- former holders of Pieris AG's capital stock held an aggregate of 20,000,000 shares of the Company´s common stock;
- holders of Marika Inc.'s common stock prior to the closing of the Acquisition hold an aggregate of 2,500,012 shares of the Company's common stock;
- 3,200,000 shares of common stock were reserved for issuance under the 2014 Employee, Director and Consultant Equity Incentive Plan of Pieris Pharmaceuticals, Inc. (the "Pieris Plan") As of December 31, 2014, options to purchase 2,519,500 shares of the Company´s common stock have been issued under the Pieris Plan to executive officers, directors, employees and consultants. As a result of such grants, 680,500 shares of the Company´s common stock are available for future issuance under the Pieris Plan.

Private Placement

On December 17, 2014, subsequent to the Acquisition, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain accredited investors (the "Investors") providing for the issuance and sale to such Investors of an aggregate of 6,779,510 shares of the Company´s common stock in a private placement offering conducted through a series of closings occurring in December 2014, at a purchase price per share of $2.00 and for aggregate gross proceeds to the Company of $13.6 million (the "Private Placement"). After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.0 million. Northland Securities, Inc. and Katalyst Securities, LLC served as co-exclusive placement agents (the "Placement Agents") for the Private Placement.

The Securities Purchase Agreement also contains certain anti-dilution provisions. Those anti-dilution provisions provide that if the Company issues and sells equity securities or equity-linked or related securities at a purchase price per share of lower than $2.00 within the 180-day period following December 17, 2014, each Investor in the Private Placement shall be entitled to receive such number of additional shares of the Company´s common stock as they would have received had such lower purchase price per share been applicable in the Private Placement.

At the closings of the Private Placement the Company issued to the Placement Agents and their designees, warrants (the Placement Warrants) to acquire up to 542,360 shares of its common stock at an exercise price of $2.00 per share. Each of the Placement Warrants is exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance. For more information refer to Note 10 *Warrants*.

As result of the Acquisition and the Private Placement the Company has 29,279,522 shares of common stock issued and outstanding with a share capital of $29,280 as of December 31, 2014.

9. Stock-Based Compensation

In December 2014, the Board of Directors and stockholders adopted the Pieris Plan, which became effective upon closing of the Acquisition. The Pieris Plan is intended to encourage ownership of common stock by the Company´s employees and directors and certain of their consultants, including employees of Pieris AG, in order to attract and retain such people, to induce them to work for the benefit of the Company and to provide additional incentive for them to promote the Company´s success. The Pieris Plan reserves 3,200,000 shares of the Company´s common stock for issuance. In addition the Pieris Plan provides for an "evergreen" provision whereby the number of shares of the Company´s common stock reserved for issuance under the Pieris Plan shall be automatically increased on January 1 of each of year commencing in fiscal 2016 by the lesser of (i) 1,000,000 shares, (ii) 4% of the number of shares of the Company´s common stock outstanding on such date, and (iii) such other amount determined by the

Compensation committee of the Board of Directors. As of December 31, 2014, options to purchase 1,430,000 shares of the Company's common stock have been granted under the Pieris Plan to its executive officers and directors, and options to purchase 1,089,500 shares have been granted under the Pieris Plan to other employees and consultants. Expenses to consultants totaled $131,984 and are recognized in general and administrative expense. As a result of such grants, 680,500 shares of the Company's common stock remain available for future issuances under the Pieris Plan.

Stock options granted under the Pieris Plan may be either incentive stock options ("ISOs"), or nonqualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally three years) and the exercise prices. Options have a maximum term of ten years. The exercise price of stock options granted under the Pieris Plan must be at least equal to the fair market value of the common stock on the date of grant. Total stock-based compensation expense, related to all share-based awards under the Pieris Plan to executive officers, directors, employees and consultants recognized during the year ended 2014, was comprised of the following:

	December 31, 2014
Research and Development	$ 7,623
General and administrative	563,759
Total stock-option expense	$571,382

The fair value of option grants was estimated using the Black-Scholes model. The following table describes the weighted-average assumptions used for calculating the value of options granted for the year ended December 31, 2014:

	2014
Dividend yield	0.0%
Expected volatility	74.66%
Weighted average risk-free interest rate	1.77%
Expected term	5.6-5.8 years

A summary of the Company's stock option activity and related information is as follows:

	Number of shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2013	—	$ —	—
Options granted	2,519,500	$2.00	5.6-5.8 years
Options exercised	—	—	—
Options canceled or expired	—	—	—
Outstanding at December 31, 2014	2,519,500	$2.00	5.6-5.8 years
Vested or expected to vest at December 31, 2014	423,750	$2.00	—
Exercisable at December 31, 2014	—	$ —	—

The weighted-average grant date fair value for awards granted during the year ended December 31, 2014 was $3,248,413. There were no options exercised during the years ended December 31, 2014 and 2013. The total fair value of shares vested in the year ended December 31, 2014 was approximately $543,926. No shares were vested in the year ended December 31, 2013.

The unrecognized share-based compensation expense related to employee stock option awards at December 31, 2014, is $2,588,411, which will be recognized over a weighted-average service period of 3 years.

10. Warrants

In connection with the Private Placement, the Company issued the Placement Warrants to acquire a combined up to 542,360 shares of its common stock at an exercise price of two dollars per share ($2.00) to the Placement Agents and their designees. The Placement Warrants are exercisable at any time at the option of the holder until the five year anniversary of its date of issuance. The number of shares of common stock issuable upon the exercise of each Placement Warrant is adjustable in the event of certain stock dividends, stock splits, combinations of shares and similar transactions. Upon exercise, the aggregate exercise price of the warrants issued are payable by the holders in cash.

The Company estimated the fair value of the Placement Warrants as of the grant date to be $664,064 and recognized the full amount in general and administrative expense for the year ended December 31, 2014.

Pursuant to ASC 815-15 and ASC 815-40, the fair value of the Placement Warrants was recorded as equity awards on the grant dates. The Placement Warrants were valued at their grant dates using the Black-Scholes pricing model and the following weighted average assumptions:

	December 31, 2014
Dividend yield	0.00%
Expected volatility	74.66%
Weighted average risk-free interest rate	1.61%
Expected term (years)	5.00

11. Accrued Expenses

Accrued expenses consist of the following:

	December	
	2014	2013
Accrued expenses		
Accrued expenses bonus payments	$ 252,953	$137,660
Accrued expenses severance payments	—	319,031
Payroll related accruals	79,939	90,549
Accrued professional fees	403,451	—
Other accrued expenses	7,523	12,389
Total amount of accrued expenses	743,866	559,629
Accrued expenses non-current		
Reserve for litigation with TUM	327,937	373,059
Accrued expenses Restoration	6,051	6,883
Total amount of accrued expenses non-current	333,988	379,942
Total amount of accrued expenses	$1,077,854	$939,571

12. Related-Party Transactions

Research and License Agreement with Technische Universität München

On July 4, 2003, the Company entered into the TUM License Agreement, which was subsequently renewed and, on July 26, 2007, superseded and replaced. The agreement established a joint research effort led by Prof. Arne Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin® technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin

scaffolds. Prof. Dr. Skerra was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the consolidated financial statements in this report. The Company provided certain funding for TUM research efforts performed under the agreement.

As a result of research efforts to date under the agreement, the Company holds a worldwide exclusive license under its license agreement with TUM to multiple patents and patent applications, including an exclusive license to an issued U.S. patent, which patent will expire in 2027 (subject to a possible term adjustment period). The Company also holds an exclusive license to an issued U.S. patent No. 8,420,051, which patent is expected to expire in 2029. The Company bears the costs of filing, prosecution and maintenance of patents assigned or licensed to the Company under the agreement.

As consideration for the assigned patents and licenses above, the Company is required to pay certain development milestones to TUM. The Company is also obliged to pay low-single-digit royalties, including annual minimum royalties, on sales of such products incorporating patented technologies. If the Company grants licenses or sublicenses to those patents to third parties, the Company will be obliged to pay a percentage of the resulting revenue to TUM. The Company´s payment obligations are reduced by the Company´s proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement. The Company can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate the rights in patents assigned to the Company.

The Company has incurred the following expenses related to TUM (excluding value added taxes):

	Years ended December 31,	
	2014	2013
Transfer of licenses and protective rights	$66,461	$66,390
Research	—	22,573
Total expenses incurred with TUM	$66,461	$88,963

The Company has recorded $327,937 and $373,059 as of December 31, 2014 and 2013, respectively, related to the amounts due under the TUM License Agreement (see Note 13 *Commitments and Contingencies*).

The part of the agreement requiring the Company to make payments for research conducted by TUM expired in February 2013 with no further obligations by the Company.

EUROCALIN/FP7 Government Grant

TUM is a member of the EUROCALIN consortium and thus is entitled to receive payments under the grant agreement for research activities. Research activities are carried out by Prof. Dr. Skerra, who was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the financial statements in this report. The government grant agreement with FP7 is further discussed in Note 4—Revenue.

Consulting Contract between Prof. Dr. Arne Skerra and the Company

In 2001, the Company entered into a Consulting Agreement with Prof. Dr. Skerra, pursuant to which Prof. Dr. Skerra provides advice regarding the use of new proteins, in particular Anticalin® proteins and antibodies, for the purpose of research and development. The Consulting Agreement has an unlimited term but can be terminated by the Company upon three months' notice with effect from the end of a month and by Prof. Dr. Skerra upon one year's notice with effect from the end of a year. Under the Consulting Agreement, the Company incurred and paid to Prof. Dr. Skerra consulting fees of $26,593 and $26,556 for the years ended December 31, 2014 and 2013, respectively.

Convertible Stockholder Loan

Four significant stockholders of the Company—Orbimed Private Investments III, LP, Gilde Europe Food & Agribusiness Fund B.V., The Global Life Science Ventures Funds (consists of The Global Life Science Venture Funds II GmbH & Co. KG, i-L. and The Global Life Science Venture Funds II Limited Partnership) and Coöperative AAC LS U.A. (Forbion B.V.)—participated as investors in the Bridge Loans as related parties. The Bridge Loans are further discussed in Note 7 *Debt*.

Receivables from Issuance of Shares

In connection with the issuance of nominal stock, payments of the share premium into additional paid in capital were deferred. Amounts were deferred for Claus Schalper and Prof. Dr. Skerra among others. During 2008 through July 31, 2013, Mr. Schalper was the Chief Financial Officer of Pieris AG, and since August 1, 2013, has served as a consultant to Pieris Operating. During 2001 and through October 10, 2014, Prof. Dr. Skerra was the deputy chairman of Pieris AG's supervisory board. In connection with the consummation of the Acquisition, the Company waived all deferred payment claims against the aforementioned stockholders.

13. Commitments and Contingencies

Licensing Commitments

The Company has license agreements with two parties under which the Company is obliged to pay annual license fees. One agreement is between IBA GmbH and the Company which requires annual license payments of $36,303 and relates to licenses for Strep-tag technology that represent tool technologies and which are used for research purposes only. The agreement expires in 2024.

Another license agreement exists between TUM and the Company (see Note 12 *Related-Party Transactions*). Under this agreement, the Company is obliged to pay an annual license fee of $60,505 to TUM. The agreement expires in 2027.

The table below shows the annual license fee commitments under the two agreements as of December 31, 2014:

	License payments
2015	$ 96,808
2016	96,808
2017	96,808
2018	96,808
2019	96,808
Thereafter	665,555
Total minimum license payments	$1,149,595

Leases

The Company leases office and laboratory space in Freising, Germany. The lease has a defined termination date and can be cancelled with a notification period of eight months at the end of each quarter.

The Company's contractual commitments of the non-cancellable portion under this operating lease as of December 31, 2014 are as follows:

	Total
2015	$176,190

Rent expense under the Company's operating lease was $268,621 and $289,991 for the years ended December 31, 2014 and 2013, respectively. Rent expense of $72,600 and $72,498 was recognized as General and Administrative expenses and $217,799 and $217,493 was recognized as Research and Development expenses in the income statement for the years ended December 31, 2014 and 2013, respectively.

TUM Arbitration

Under the TUM License Agreement, the Company is required to make payments to TUM based on the Company's revenues generated from entering into sub-licensing agreements with any third party with respect to University Inventions and/or Joint Inventions (each as defined in the TUM License Agreement). These revenues include upfront license payments as well as milestone payments received by the Company from third parties. The Company has signed six such sub-licensing agreements between 2004 and 2012 (the period under dispute), under which it has recorded revenues. The Company acknowledges an obligation to TUM; however, the parties disagree regarding the amount due.

On March 20, 2014, the Company instituted arbitration proceedings against TUM to address issues regarding the calculation of payments due from the Company to TUM under TUM License Agreement. Under the agreement, TUM has exclusively licensed, or in some cases assigned, to the Company certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, the Company agreed to pay to TUM certain annual license fees, milestones and royalties for its own proprietary drug development and sales, as well as a variable fee as a function of out-licensing revenues (the "Out-License Fee"), where such Out-License Fee is creditable against annual license payments to TUM. As required by the agreement, the Company provided to TUM its calculation of the Out-License Fee for the period beginning July 4, 2003 and ending on December 31, 2012 in the amount of €0.3 million ($0.3 million) excluding value-added tax. TUM has asserted that the Out-License Fee for this period amounts to €2.5 million ($3.0 million) excluding value-added tax and has threatened to terminate the license agreement if the Out-License Fee is not paid. The Company instituted arbitration to request confirmation that The Company's calculation of the payments owed to TUM is accurate and will govern all current and future payments due in respect of the Out-License Fee under the agreement.

In April 2014, TUM argued to the arbitrators that it is not the proper party to be sued under the action for a declaratory arbitration decision brought by the Company in relation to the TUM Licensing Agreement, and that instead, it is the Free State of Bavaria that is the proper respondent to the action. The Company has responded that TUM has capacity to be sued in relation to any disputes arising from and regarding contractual provisions of the TUM Licensing Agreement and is thus also the proper respondent in the action. In accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit, each party to the arbitration proceeding has appointed one arbitrator and the party-named arbitrators collectively selected the third arbitrator as the chairman of the arbitration panel. The Company has estimated the probable loss and recorded the amount as a liability on its balance sheet as of December 31, 2014 and 2013 of $327,937 and $373,059 respectively. The Company has concluded that the potential of a loss above the estimated probable loss is remote, however it is possible additional losses may occur.

On December 1, 2014, TUM filed its statement of defense, maintaining its earlier calculation of the Out-License Fee. On December 23, 2014, TUM filed a counterclaim in the amount of €2,529,400 ($3,060,827) to suspend the statute of limitations on its claims.

14. Subsequent Events

TUM Arbitration

On January 12, 2015, the Company filed a reply brief in response to TUM's defense. The arbitration panel held its first hearing in Munich, Germany on January 20, 2015, however the arbitration panel did not come to a conclusion on whether TUM is the proper respondent in the action or on the merits of the case. The panel had previously indicated that it will first decide the issue of whether TUM is the proper respondent in this action. The

panel resolved that the value in dispute for both parties' claims and counterclaims would be fixed at €3.5 million ($4.2 million), as the calculation of the outstanding Out-Licensing Fee also impacts future payments. The Company submitted a reply brief responding to TUM's defense and counterclaim to the panel on March 3, 2015. TUM must submit a rebuttal brief by March 31, 2015. The Company believes the amount in dispute is without merit and such subsequent events does not impact the probable loss accrued for as of December 31, 2014.

Corporate Information

BOARD OF DIRECTORS

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

Chau Khuong (Chairman)
Partner, OrbiMed Advisors LLC, USA

Christina Takke, Ph.D.
Partner, Forbion Capital Partners, The Netherlands

Michael Richman
President & Chief Executive Officer, Amplimmune, USA

Steven Prelack
Senior Vice President and Chief Operating Officer, VetCor

Jean-Pierre Bizzari, M.D.
Former Executive Vice President, Group Head, Clinical Oncology Development, Celegene Corporation

EXECUTIVE OFFICERS

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

Darlene Deptula-Hicks
Acting Chief Financial Officer, Secretary & Treasurer

CORPORATE HEADQUARTERS

Pieris Pharmaceuticals, Inc.
Lise-Meitner-Strasse 30
85354 Freising, Germany
T: + 49 (0) 8161 14 11 400
www.pieris.com

ANNUAL MEETING

Tuesday, June 30, 2015 - 10:00 am
Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
666 Third Avenue, 32nd Floor
New York, NY 10017

TRANSFER AGENT AND REGISTRAR

Globex Transfer, LLC
780 Deltona Blvd.
Suite 202
Deltona, FL 32725
T: 813-344-4490
www.globextransfer.com

LEGAL COUNSEL

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111

AUDITORS

Ernst & Young GmbH
WirtschaftsprüfungsgesellschaftArnulfstr.
59, 80636 München, Germany

FORWARD-LOOKING STATEMENTS

This annual report contains certain forward-looking statements. Actual results may differ materially from those predicted herein due to certain risks and uncertainties inherent in the Company's business, which are discussed in the Company's Form 10-K for the fiscal year ended December 31, 2014. Further information on the factors and risks that could affect the Company's business, financial condition and results of operations are contained in Pieris Pharmaceuticals, Inc.'s public disclosure filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov

pieris
PHARMACEUTICALS

Lise-Meitner-Strasse 30
85354 Freising, Germany
+49 (0) 8161 14 11 400